

# VICAL INC

## FORM 10-Q (Quarterly Report)

Filed 11/07/12 for the Period Ending 09/30/12

Address	10390 PACIFIC CENTER COURT . SAN DIEGO, CA 92121-4340
Telephone	858-646-1100
CIK	0000819050
Symbol	VICL
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

---

---

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

---

**FORM 10-Q**

---

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

For the quarterly period ended September 30, 2012

Or

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

For the transition period from            to            .

Commission File Number: 000-21088

---

**VICAL INCORPORATED**

(Exact name of registrant as specified in its charter)

---

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**93-0948554**  
(I.R.S. Employer  
Identification No.)

**10390 Pacific Center Court**  
**San Diego, California**  
(Address of principal executive offices)

**92121**  
(Zip code)

**(858) 646-1100**  
(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

---

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

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

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

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Smaller reporting company ☐

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Total shares of common stock outstanding at October 31, 2012: 86,134,911

---

---

---

**Table of Contents****VICAL INCORPORATED****FORM 10-Q****INDEX****PART I. FINANCIAL INFORMATION****ITEM 1. Financial Statements**

Balance Sheets (unaudited) as of September 30, 2012, and December 31, 2011 3

Statements of Comprehensive Income (Loss) (unaudited) for the three and nine months ended September 30, 2012 and 2011 4

Statements of Cash Flows (unaudited) for the nine months ended September 30, 2012 and 2011 5

Notes to Financial Statements (unaudited) 6

**ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations 13**

**ITEM 3. Quantitative and Qualitative Disclosures About Market Risk 20**

**ITEM 4. Controls and Procedures 21**

**PART II. OTHER INFORMATION**

**ITEM 1A. Risk Factors 22**

**ITEM 5. Other Information 31**

**ITEM 6. Exhibits 32**

**SIGNATURE 33**

**PART I. FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

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

	September 30, <u>2012</u>	December 31, <u>2011</u>
<b><u>ASSETS</u></b>		
Current assets:		
Cash and cash equivalents	\$ 53,150	\$ 38,696
Marketable securities, available-for-sale	33,743	8,733
Restricted cash	3,059	2,998
Receivables and other assets	<u>2,537</u>	<u>3,130</u>
Total current assets	92,489	53,557
Long-term investments	2,250	5,928
Property and equipment, net	5,572	6,226
Intangible assets, net	2,822	2,871
Other assets	<u>192</u>	<u>191</u>
Total assets	<u>\$ 103,325</u>	<u>\$ 68,773</u>
<b><u>LIABILITIES AND STOCKHOLDERS' EQUITY</u></b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 5,591	\$ 6,362
Deferred revenue	<u>—</u>	<u>99</u>
Total current liabilities	5,591	6,461
Long-term liabilities:		
Deferred rent	1,743	1,964
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, 86,111 and 71,913 shares issued and outstanding at September 30, 2012, and December 31, 2011, respectively	861	719
Additional paid-in capital	435,253	384,087
Accumulated deficit	(340,388)	(325,038)
Accumulated other comprehensive income	<u>265</u>	<u>580</u>
Total stockholders' equity	95,991	60,348
Total liabilities and stockholders' equity	<u>\$ 103,325</u>	<u>\$ 68,773</u>

See accompanying notes to unaudited financial statements

## Table of Contents

**VICAL INCORPORATED**  
**STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**  
(In thousands, except per share data)  
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Revenues:				
Contract and grant revenue	\$ 1,682	\$ 1,360	\$ 4,267	\$ 2,607
License and royalty revenue	493	25,259	10,933	25,479
Total revenues	2,175	26,619	15,200	28,086
Operating expenses:				
Research and development	3,682	5,505	13,901	14,004
Manufacturing and production	3,853	2,343	9,258	7,697
General and administrative	2,420	2,379	7,898	7,161
Total operating expenses	9,955	10,227	31,057	28,862
Income (loss) from operations	(7,780)	16,392	(15,857)	(776)
Other income (expense):				
Investment and other income, net	54	39	507	107
Net income (loss)	<u>\$ (7,726)</u>	<u>\$16,431</u>	<u>\$(15,350)</u>	<u>\$ (669)</u>
Basic net income (loss) per share	<u>\$ (0.09)</u>	<u>\$ 0.23</u>	<u>\$ (0.18)</u>	<u>\$ (0.01)</u>
Diluted net income (loss) per share	<u>\$ (0.09)</u>	<u>\$ 0.22</u>	<u>\$ (0.18)</u>	<u>\$ (0.01)</u>
Weighted average shares used in computing basic net income (loss) per share	<u>86,408</u>	<u>72,075</u>	<u>85,762</u>	<u>71,987</u>
Weighted average shares used in computing diluted net income (loss) per share	<u>86,408</u>	<u>73,739</u>	<u>85,762</u>	<u>71,987</u>
Comprehensive income (loss)	<u>\$ (7,686)</u>	<u>\$16,774</u>	<u>\$(15,665)</u>	<u>\$ (190)</u>

See accompanying notes to unaudited financial statements

## Table of Contents

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

	Nine Months Ended September 30,	
	2012	2011
Cash flows from operating activities:		
Net loss	\$(15,350)	\$ (669)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,478	1,746
Write-off of abandoned patents	71	—
Gain on sale of property and equipment	(9)	—
Compensation expense related to stock options and awards	2,578	2,360
Changes in operating assets and liabilities:		
Receivables and other assets	593	(1,436)
Accounts payable and accrued expenses	(816)	(913)
Deferred revenue	(99)	—
Deferred rent	(176)	(112)
Net cash provided by (used in) operating activities	<u>(11,730)</u>	<u>976</u>
Cash flows from investing activities:		
Proceeds from the sale of marketable securities	3,750	—
Maturities of marketable securities	13,954	15,930
Purchases of marketable securities	(39,412)	(22,549)
Purchases of property and equipment	(529)	(290)
Proceeds from the sale of property and equipment	9	—
Patent expenditures	(318)	(315)
Net cash used in investing activities	<u>(22,546)</u>	<u>(7,224)</u>
Cash flows from financing activities:		
Net proceeds from issuance of common stock	48,931	130
Payment of withholding taxes for net settlement of restricted stock units	(201)	(134)
Net cash provided by (used in) financing activities	<u>48,730</u>	<u>(4)</u>
Net increase (decrease) in cash and cash equivalents	14,454	(6,252)
Cash and cash equivalents at beginning of period	38,696	47,320
Cash and cash equivalents at end of period	<u>\$ 53,150</u>	<u>\$ 41,068</u>

See accompanying notes to unaudited financial statements

**VICAL INCORPORATED**  
**NOTES TO FINANCIAL STATEMENTS**  
**September 30, 2012**  
**(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, 2012, and for the three and nine months ended September 30, 2012 and 2011, 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, 2011, 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 which reflects management's intention to use the proceeds from sales of these securities to fund its operations, as necessary. 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, net of tax, 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, 2012, and December 31, 2011, restricted cash of \$3.1 and \$3.0 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. Certain of the Company's revenue is generated through manufacturing contracts and stand-alone license agreements.

---

## Table of Contents

The Company has entered into multiple-element arrangements. 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.

Effective January 1, 2011, the Company follows the provisions of ASU No. 2009-13 “Multiple-Deliverable Revenue Arrangements” for all multiple element agreements, including contract manufacturing, contract services and license agreements. Under the revised guidance, the delivered item(s) has value to the customer on a standalone basis and, 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.

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. 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, or 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. 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 license is identified as a separate unit of accounting and the amounts allocated to the license are recognized upon the delivery of the license, assuming the other revenue recognition criteria have been met. However, if the amounts allocated to the license through the relative selling price allocation exceed the upfront license fee, the amount recognized upon the delivery of the license is limited to the upfront fee received. If facts and circumstances dictate that the license does not have standalone value, the transaction price, including any upfront license fee payments received, are allocated to the identified separate units of accounting and recognized as those items are delivered.

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 of accounting under ASU 2010-17. 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.

### *Contract Services, Grant and Royalty Revenue*

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. Royalties to be received based on sales of licensed products by the Company’s partners incorporating the Company’s licensed technology are recognized when received.



## Table of Contents

### Net 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 loss per share excludes any assumed exercise of stock options and warrants, and any assumed issuance of common stock under restricted stock units, or RSUs, as the effect would be antidilutive. Common stock equivalents of 1.6 million for the three months ended September 30, 2012, were excluded from the calculation because of their antidilutive effect. Common stock equivalents of 1.5 million and 1.3 million for the nine months ended September 30, 2012 and 2011, respectively, were excluded from the calculation because of their antidilutive effect.

The weighted average number of shares used to compute diluted net income per share includes any assumed exercise of stock options under the treasury stock method, and the assumed issuance of common stock under 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.

### 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 was effective for fiscal years and interim periods beginning after December 15, 2011. The Company adopted these provisions as of January 1, 2012. The adoption did not have a material impact on the Company's 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 was effective on a prospective basis for annual and interim reporting periods beginning on or after December 15, 2011. The Company adopted these provisions as of January 1, 2012. 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 Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Research and development	\$245	\$229	\$ 803	\$ 727
Manufacturing and production	53	43	158	125
General and administrative	437	475	1,617	1,508
Total stock-based compensation expense	<u>\$735</u>	<u>\$747</u>	<u>\$2,578</u>	<u>\$2,360</u>

During the nine months ended September 30, 2012 and 2011, the Company granted stock-based awards with a total estimated value of \$3.9 million and \$3.8 million, respectively. At September 30, 2012, total unrecognized estimated compensation expense related to unvested stock-based awards granted prior to that date was \$3.7 million, which is expected to be recognized over a weighted-average period of 1.6 years. Stock-based awards granted during the nine months ended September 30, 2012 and 2011, were equal to 2.2% and 3.6%, respectively, of outstanding shares of common stock at the end of the applicable period.

## Table of Contents

### 3. OTHER BALANCE SHEET ACCOUNTS

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

	September 30,	December 31,
	2012	2011
Clinical trial accruals	\$ 957	\$ 1,681
Employee compensation	3,199	3,653
Accounts payable	659	351
Other accrued liabilities	776	677
Total accounts payable and accrued expenses	<u>\$ 5,591</u>	<u>\$ 6,362</u>

### 4. MARKETABLE SECURITIES, AVAILABLE FOR SALE

The following is a summary of available for sale marketable securities (in thousands):

	Amortized	Unrealized	Unrealized	
	Cost	Gain	Loss	Market Value
<b>September 30, 2012</b>				
U.S. treasuries	\$ 10,110	\$ 1	\$ —	\$10,111
Government-sponsored enterprise securities	10,860	—	1	10,859
Corporate bonds	12,577	—	4	12,573
Certificates of deposit	200	—	—	200
	<u>\$ 33,747</u>	<u>\$ 1</u>	<u>\$ 5</u>	<u>\$33,743</u>
	Amortized	Unrealized	Unrealized	
	Cost	Gain	Loss	Market Value
<b>December 31, 2011</b>				
U.S. treasuries	\$ 1,008	\$ 2	\$ —	\$1,010
Government-sponsored enterprise securities	7,200	—	2	7,198
Certificates of deposit	525	—	—	525
	<u>\$ 8,733</u>	<u>\$ 2</u>	<u>\$ 2</u>	<u>\$8,733</u>

At September 30, 2012, \$13.4 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, 2012. As of September 30, 2012, none of the securities had been in a continuous unrealized loss position longer than one year.

### 5. LONG-TERM INVESTMENTS

In March 2012, the Company sold two auction rate securities classified as long-term investments with a par value of \$4.0 million. Included in interest and other income for the nine months ended September 30, 2012, is a gain of \$0.3 million related to the sale.

As of September 30, 2012, the Company held an auction rate security with a par value of \$2.5 million. This auction rate security has not experienced a successful auction since the liquidity issues experienced in the global credit and capital markets in 2008. As a result the security is classified as a long-term investment as it is scheduled to mature in 2038. The security was rated BBB by Standard and Poor's as of September 30, 2012. The security continues to pay interest according to its stated terms.

The valuation of the Company's auction rate security is subject to uncertainties that are difficult to predict. The fair value of the security is estimated utilizing a discounted cash flow analysis. The key drivers of the valuation model include the expected term, collateralization underlying the security investment, the creditworthiness of the counterparty, the timing of expected future cash flows, discount rates, liquidity and the expected holding period. The security was also compared, when possible, to other observable market data for securities with similar characteristics. Based on the valuation of the security, the Company has recognized cumulative losses of \$0.5 million as of September 30, 2012, none of which were realized during the

## Table of Contents

three or nine months ended September 30, 2012. The losses when recognized are included in investment and other income. The market value of the security has partially recovered. Included in other comprehensive income are unrealized gains of \$0.1 million and \$0.3 million for the nine months ended September 30, 2012 and 2011, respectively. As of September 30, 2012, the Company had recorded cumulative unrealized gains of \$0.4 million. The resulting carrying value of the auction rate security at September 30, 2012, was \$2.3 million. Any future decline in market value may result in additional losses being recognized.

## 6. FAIR VALUE MEASUREMENTS

The Company measures fair value as 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 at the measurement date. 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. Fair value measurements are based on 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 equivalents, marketable securities and long-term investments measured at fair value are classified in the table below in one of the three categories described above (in thousands):

September 30, 2012	Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Certificates of deposit	\$ 200	\$ —	\$ —	\$ 200
Money market funds	27,692	—	—	27,692
U.S. treasuries	10,111	—	—	10,111
Corporate bonds	—	12,573	—	12,573
Government-sponsored enterprise securities	—	10,859	—	10,859
Auction rate securities	—	—	2,250	2,250
	<u>\$38,003</u>	<u>\$23,432</u>	<u>\$2,250</u>	<u>\$63,685</u>

  

December 31, 2011	Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Certificates of deposit	\$ 525	\$ —	\$ —	\$ 525
Money market funds	12,778	—	—	12,778
U.S. treasuries	1,010	—	—	1,010
Government-sponsored enterprise securities	—	7,198	—	7,198
Auction rate securities	—	—	5,928	5,928
	<u>\$14,313</u>	<u>\$7,198</u>	<u>\$5,928</u>	<u>\$27,439</u>

The Company's investments in U.S. treasury securities, certificates of deposit and money market funds are valued based on publicly available quoted market prices for identical securities as of September 30, 2012. The Company determines the fair value of corporate bonds and other government-sponsored enterprise related securities with the aid of valuations provided by third parties using proprietary valuation models and analytical tools. These valuation models and analytical tools use market pricing or similar instruments that are both objective and publicly available, including matrix pricing or reported trades, benchmark yields, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids and/or offers. The Company validates the valuations received from its primary pricing vendors for its level 2 securities by examining the inputs used in that vendor's pricing process and determines whether they are reasonable and observable. The Company also compares those valuations to recent reported trades for those securities. The Company did not adjust any of the valuations received from these independent third parties with respect to any of its level 2 securities at September 30, 2012. The Company did not reclassify any investments between level categories during the nine months ended September 30, 2012. The valuation of the Company's investments in auction rate securities are more fully described in Note 5.

## Table of Contents

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

	Nine Months Ended September 30,
	2012
Balance at December 31, 2011	\$ 5,928
Total net realized gains included in earnings	(590)
Total net unrealized gains included in other comprehensive income	72
Sales of Level 3 securities	(3,160)
Balance at September 30, 2012	\$ 2,250
Total gains or losses for the period included in net income attributable to the change in unrealized gains or losses relating to assets still held at the reporting date	\$ —

## 7. 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 patent enforcement actions, 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.

## 8. STOCKHOLDERS' EQUITY

In January 2012, the Company sold 13,909,692 shares of its common stock in a public offering at a price to the public of \$3.75 per share. Net proceeds from the offering, after deducting underwriting discounts and commissions and other offering expenses payable by the Company, totaled \$48.7 million. All of the shares of common stock were offered pursuant to two effective shelf registration statements.

## 9. 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 cytomegalovirus, or CMV, glycoprotein B and/or phosphoprotein 65, including TransVax™ but excluding CyMVectin™.

Under the terms of the license agreements, Astellas paid a nonrefundable upfront license fee of \$25.0 million in 2011. The Company also received an additional \$10.0 million milestone payment upon finalization of the general trial design for a Phase 3 registration trial of TransVax™ in hematopoietic stem cell transplant recipients which occurred in March of 2012. The Company recognized \$10.5 million in license revenue under the Astellas agreements during the nine months ended September 30, 2012, which included the aforementioned \$10.0 million milestone.

In August 2012 the Company amended its license and supply agreements with Astellas to, among other things, extend the time period that the Company is obligated to supply licensed products for commercial use to Astellas, at Astellas' expense, modify the allocation of \$95.0 million of milestone payments among certain milestones through commercial launch and modify the structure of the royalties on net sales from a fixed double digit royalty to tiered double digit royalties.

Under the terms of the agreements the Company is also performing research and development services which are being paid for by Astellas. During the three and nine months ended September 30, 2012, the Company recognized \$1.6 million and \$3.9 million, respectively, of revenue related to these contract services.

**10. SUBSEQUENT EVENT**

On November 7, 2012, the Company entered into an At-The-Market Equity Offering Sales Agreement with Stifel, Nicolaus & Company, Incorporated, or Stifel, under which the Company may issue and sell up to \$50,000,000 of shares of our common stock from time to time. Under the Sales Agreement, the Company will set the parameters for the sale of shares, including the number of shares to be issued and any minimum price below which sales may not be made. Subject to the terms and conditions of the Sales Agreement, shares may be sold through Stifel acting as sales agent or directly to Stifel acting as principal, by means of ordinary brokers' transactions on the NASDAQ Global Market, in privately negotiated transactions or otherwise at market prices prevailing at the time of sale, at prices related to prevailing market prices or at negotiated prices. Any sales other than by methods deemed to be an "at the market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act, will require the Company's prior consent. Stifel is obligated to use commercially reasonable efforts in conducting sales activities consistent with its normal trading and sales practices. The Sales Agreement may be terminated by the Company upon prior notice to Stifel or by Stifel upon prior notice to the company, or at any time under certain circumstances, including but not limited to the occurrence of a material adverse change in the company.

The Sales Agreement provides that Stifel will be entitled to compensation for its services in an amount of 2.5% of the gross proceeds from the sale of shares sold through Stifel under the Sales Agreement. The company has no obligation to sell any shares under the Sales Agreement, and may at any time suspend offers under the Sales Agreement. The Company agreed in the Sales Agreement to provide indemnification and contribution to Stifel against certain liabilities, including liabilities under the Securities Act, and to reimburse Stifel for certain legal expenses incurred in connection with the Sales Agreement.

**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 1933, 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, 2011, and in our other filings with the SEC, and those identified in Part II, Item 1A entitled "Risk Factors" beginning on page 22 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 that 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 three 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<sup>®</sup> 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 preclinical program, with an allowed investigational new drug application, or IND, using our CyMVectin<sup>™</sup> prophylactic vaccine formulated with our proprietary Vaxfectin<sup>®</sup> 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<sup>®</sup> 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, Bristol-Myers Squibb Company, or Bristol-Myers Squibb, 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, or MIT. 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.

## Table of Contents

### 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 <sup>1</sup>	Lead Developer
<b><i>Independent Programs</i></b>			
Allovectin <sup>®</sup> cancer immunotherapeutic	First-line treatment for metastatic melanoma	Phase 3	Vical
CyMVectin <sup>™</sup> prophylactic vaccine for cytomegalovirus	Prevent infection before pregnancy to preclude fetal transmission	Allowed Investigational New Drug Application	Vical
Therapeutic and prophylactic vaccines for herpes simplex type 2 virus	Prevent and protect against recurring flare-ups, reduce viral shedding and transmission	Preclinical	Vical
<b><i>Corporate Collaborations</i></b>			
TransVax <sup>™</sup> 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 <sup>®</sup> 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 <sup>®</sup> -IHN prophylactic vaccine for infectious hematopoietic necrosis virus	Prevent infection and disease in farm-raised salmon when exposed to infected wild salmon	Marketed in Canada	Aqua Health (Novartis)
ONCEPT <sup>™</sup> therapeutic cancer vaccine encoding human tyrosinase	Adjunct treatment to increase survival time of dogs with oral melanoma	Marketed in the United States	Merial
<b><i>Government Collaborations</i></b>			
Prophylactic and/or therapeutic HIV vaccine	Prevent and/or treat infection, disease, and/or viral shedding	Phase 2b	NIH
Tetavalent dengue vaccine	Prevent dengue disease caused by all 4 dengue serotypes	Phase 1	Naval Medical Research Center

<sup>1</sup> “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.



## Table of Contents

### Recent Events

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

- In September 2012, we entered into a worldwide, nonexclusive license with Bristol-Myers Squibb for our patented platform DNA immunization technology and our Vaxfectin<sup>®</sup> adjuvant for use in the production of antibodies. Under the agreement, Bristol-Myers Squibb will use our technology to generate antibodies with potential therapeutic uses in humans. We will also provide specified quantities of the Vaxfectin<sup>®</sup> adjuvant to Bristol-Myers Squibb from time to time.
- In October 2012, George J. Morrow, former Executive Vice President of Global Commercial Operations at Amgen, Inc., was appointed to Vical's Board of Directors. Mr. Morrow's previous career encompassed significant accomplishments in commercial operations, sales and marketing through a progression of executive management positions at Merck and Glaxo Wellcome plc.
- In September 2012, we conducted a comprehensive sweep of all active clinical sites in our Phase 3 Allovectin<sup>®</sup> melanoma trial to eliminate any time lag in death event reporting. The sweep confirmed that the target number of events has not been reached. Based on the moving average monthly event rate, we revised our projection for reaching the target number of death events to mid-2013.

### 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 \$213.4 million in revenues from these sources. Revenues by source were as follows (in millions):

Source	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Astellas supply and services contract	\$ 1.6	\$ 1.2	\$ 3.9	\$ 1.2
RapidResponse <sup>™</sup> DNA manufacturing grant	—	—	—	0.9
HSV-2 grant	—	—	—	0.2
Other contract and grants	0.1	0.2	0.4	0.3
Total contract and grant revenues	1.7	1.4	4.3	2.6
Astellas license	\$ 0.2	\$ 25.1	\$ 10.5	\$ 25.1
Other royalties and licenses	0.3	0.1	0.4	0.4
Total royalty and license revenues	0.5	25.2	10.9	25.5
Total revenues	<u>\$ 2.2</u>	<u>\$ 26.6</u>	<u>\$ 15.2</u>	<u>\$ 28.1</u>

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

Program	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Allovectin <sup>®</sup>	\$ 4.0	\$ 4.7	\$ 11.7	\$ 13.9
CMV	2.2	2.4	7.3	5.1
Other research, development, manufacturing and production	1.3	0.7	4.2	2.7
Total research, development, manufacturing and production	<u>\$ 7.5</u>	<u>\$ 7.8</u>	<u>\$ 23.2</u>	<u>\$ 21.7</u>

Since our inception through September 30, 2012, we estimate that we have spent approximately \$466 million on research, development, manufacturing and production. Our current independent development focus is on our cancer immunotherapeutic Allovectin<sup>®</sup>, novel DNA vaccines for CMV and HSV-2, and other clinical and preclinical targets.

We are conducting a Phase 3 clinical trial using Allovectin<sup>®</sup> 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



---

## Table of Contents

development agreement. We are also developing TransVax™, CyMVectin™, and HSV-2 vaccine candidates and these programs, excluding TransVax™ which we recently licensed to Astellas, will require significant additional funds to advance through development to commercialization. From inception through September 30, 2012, we have spent approximately \$162 million on our Allovecin® program and \$72 million on our CMV 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 U.S. Food and Drug Administration, or 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. Certain of our revenue is generated through manufacturing contracts and stand-alone license agreements.

We have entered into multiple-element arrangements. 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.

Effective January 1, 2011, we followed the provisions of ASU No. 2009-13 for all multiple element agreements, including contract manufacturing, contract services and license agreements. Under the revised guidance, the delivered item(s) has value to the customer on a standalone basis and, 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.

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. 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, or 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

---

## Table of Contents

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. 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 license is identified as a separate unit of accounting and the amounts allocated to the license are recognized upon the delivery of the license, assuming the other revenue recognition criteria have been met. However, if the amounts allocated to the license through the relative selling price allocation exceed the upfront license fee, the amount recognized upon the delivery of the license is limited to the upfront fee received. If facts and circumstances dictate that the license does not have standalone value, the transaction price, including any upfront license fee payments received, are allocated to the identified separate units of accounting and recognized as those items are delivered.

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 of accounting under ASU 2010-17. 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.

### *Contract Services, Grant and Royalty 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. Royalties to be received based on sales of licensed products by our partners incorporating our licensed technology are recognized when received.

### *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.

---

## Table of Contents

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, 2012, our largest group of intangible assets with finite lives included patents and patents pending for our DNA delivery technology, consisting of intangible assets with a net carrying value of approximately \$2.7 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, 2012, Compared with Three Months Ended September 30, 2011*

*Total Revenues* . Total revenues decreased \$24.4 million to \$2.2 million for the three months ended September 30, 2012, from \$26.6 million for the three months ended September 30, 2011. This decrease 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 \$0.4 million increase in contract service revenue in 2012 related to our agreements with Astellas.

*Research and Development Expenses* . Research and development expenses decreased \$1.8 million, or 33.1%, to \$3.7 million for the three months ended September 30, 2012, from \$5.5 million for the three months ended September 30, 2011. This decrease 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 during the three months ended September 30, 2011.

*Manufacturing and Production Expenses* . Manufacturing and production expenses increased \$1.5 million, or 64.4%, to \$3.9 million for the three months ended September 30, 2012, from \$2.3 million for the three months ended September 30, 2011. This increase was primarily the result of the recognition of capitalized costs during the three months ended September 30, 2012, related to the shipment of clinical trial material we manufactured for Astellas.

*General and Administrative Expenses* . General and administrative expenses increased \$41,000, or 1.7%, to \$2.4 million for the three months ended September 30, 2012, from \$2.4 million for the three months ended September 30, 2011. This increase was primarily the result of higher employee related compensation and facilities costs.

#### *Nine Months Ended September 30, 2012, Compared with Nine Months Ended September 30, 2011*

*Total Revenues* . Total revenues decreased \$12.9 million to \$15.2 million for the nine months ended September 30, 2012, from \$28.1 million for the nine months ended September 30, 2011. Our license and royalty revenue decreased by \$14.5 million, which 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 \$10.0 million of license revenue related to the achievement of a trial design milestone under our TransVax™ license agreements with Astellas during 2012.

*Research and Development Expenses* . Research and development expenses decreased \$0.1 million, or 0.7%, to \$13.9 million for the nine months ended September 30, 2012, from \$14.0 million for the nine months ended September 30, 2011. This decrease was primarily due to lower overall wages and safety study costs which were offset by the higher sub-license payment we made to the City of Hope related to the license of our TransVax™ program to Astellas.

---

## Table of Contents

*Manufacturing and Production Expenses* . Manufacturing and production expenses increased \$1.6 million, or 20.3%, to \$9.3 million for the nine months ended September 30, 2012, from \$7.7 million for the nine months ended September 30, 2011. This increase was primarily the result of higher wages due to an increase in headcount and higher scientific supplies used in manufacturing.

*General and Administrative Expenses* . General and administrative expenses increased \$0.7 million, or 10.3%, to \$7.9 million for the nine months ended September 30, 2012, from \$7.2 million for the nine months ended September 30, 2011. This increase was primarily the result of higher employee related compensation.

*Investment and Other Income, Net* . Investment and other income, net increased \$0.4 million to \$0.5 million for the nine months ended September 30, 2012, from \$0.1 million for the nine months ended September 30, 2011. This increase was primarily the result of a gain recognized on the sale of auction rate securities during the nine months ended September 30, 2012.

## Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through private placements and public offerings of equity securities, and revenues from our operations. From our inception through September 30, 2012, we have received approximately \$213.4 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 \$420.0 million from the sale of equity securities. Cash, cash equivalents, marketable securities, and long-term investments, including restricted cash, totaled \$92.2 million at September 30, 2012, compared with \$56.4 million at December 31, 2011. The increase in our cash, cash equivalents and marketable securities for the nine months ended September 30, 2012, was primarily the result of the receipt of \$48.7 million in net proceeds related to the sale of 13.9 million of our common shares in a public offering.

Net cash (used in) provided by operating activities was \$(11.7) million and \$1.0 million for the nine months ended September 30, 2012 and 2011, respectively. The increase in net cash used in operating activities for the nine months ended September 30, 2012, compared with the prior year period, was primarily the result of a \$15 million decrease in license revenue related to our TransVax™ license agreements, which was partially offset by a decrease in accounts receivable.

Net cash used in investing activities was \$22.5 million and \$7.2 million for the nine months ended September 30, 2012 and 2011, respectively. The increase in net cash used in investing activities for the nine months ended September 30, 2012, compared with the prior year period, was primarily the result of an increase in the purchases of marketable securities.

Net cash provided by (used in) financing activities was \$48.7 million and \$(4,000) for the nine months ended September 30, 2012 and 2011, respectively. The increase in net cash provided by financing activities for the nine months ended September 30, 2012, compared with the prior year period, was the result of net proceeds received from the sale of our common stock during the nine months ended September 30, 2012.

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. We may also seek additional funding through public or private financings. We currently have on file effective shelf registration statements that allow us to raise up to an aggregate of \$203.4 million from the sale of common stock, preferred stock, debt securities and/or warrants. 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.

---

## Table of Contents

### *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 Corporation 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, 2012, is approximately \$15.1 million, of which approximately \$7.2 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 in-license 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 activities. 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 two 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 \$3.2 million if each such executive officer and other executive were terminated at September 30, 2012.

### **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 six months. Our investments are classified as available-for-sale securities.



---

## Table of Contents

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 \$0.3 million lower than the reported fair value of our investments at September 30, 2012.

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, 2012, our long-term investments included a (at par value) \$2.5 million auction rate security secured by municipal bonds. At September 30, 2012, the auction rate security we held maintained a Standard and Poor's credit rating of BBB. The auction rate security is a debt instrument with a long-term maturity and with an interest rate that is reset in short intervals through auctions. The 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 our auction rate security held at September 30, 2012. As a result, this security is currently not liquid, and we could be required to hold it until it is redeemed by the issuer or to maturity. As of September 30, 2012, we had recognized \$0.5 million of losses related to the auction rate security by adjusting its carrying value. The market value of the security has partially recovered from the lows that created the losses. As of September 30, 2012, we had recorded cumulative unrealized gains of \$0.4 million. Any future decline in market value may result in additional losses being recognized.

The valuation of our auction rate security is subject to uncertainties that are difficult to predict. The fair value of the security is estimated utilizing a discounted cash flow analysis or other type of valuation model as of September 30, 2012. The key drivers of the valuation model include the expected term, collateralization underlying the security investment, the creditworthiness of the counterparty, the timing of expected future cash flows, discount rates, and the expected holding period. This security was 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 this investment is successful or it is redeemed by the issuer or it matures. If we are unable to sell this security in the market or it is not redeemed, then we may be required to hold it to maturity. We do not anticipate a need to access the funds for operational purposes for the foreseeable future. We will continue to monitor and evaluate this investment 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 this investment 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, 2012.

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

Management has determined that there were no significant changes in our internal control over financial reporting that occurred during the three months ended September 30, 2012, 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, 2011, 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<sup>®</sup>, for which we announced the completion of enrollment of a Phase 3 clinical trial in 2010. We have an allowed Investigational New Drug Application for CyMVectin<sup>™</sup> and have begun preclinical work on a HSV-2 vaccine. We may not meet the primary endpoint of the Allovectin<sup>®</sup> trial for which a Special Protocol Assessment agreement is in place with the FDA. We may not conduct Phase 1 CyMVectin<sup>™</sup> or HSV-2 vaccine trials, 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 TransVax<sup>™</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>™</sup> but excluding CyMVectin<sup>™</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>™</sup> depends on Astellas' ability to develop, obtain regulatory approvals for and successfully commercialize TransVax<sup>™</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>™</sup>, which could adversely impact sales or future development of TransVax<sup>™</sup>,

---

## Table of Contents

- 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™, 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™ 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™, 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™ on acceptable terms, or at all, and we may be unable to pursue continued development or commercialization of TransVax™ 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 New Drug Application, or 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



---

## Table of Contents

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 \$7.3 million, \$30.4 million and \$28.6 million for the years ended December 31, 2011, 2010 and 2009, respectively. As of September 30, 2012, we had incurred cumulative net losses totaling approximately \$340.4 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 currently have on file shelf registration statements that allow us to raise up to an aggregate of \$203.4 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.

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;

---

## Table of Contents

- 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.

---

## Table of Contents

***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<sup>®</sup> Phase 2 trial conducted in 2000, died from progressive disease more than two months after receiving Allovectin<sup>®</sup> 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<sup>®</sup> 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>™</sup> Phase 2 trial, we administered TransVax<sup>™</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, 2012, we were the assignee or co-assignee of 80 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, 2012, we were also prosecuting 56 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 AIA, was signed into law on September 16, 2011 and significantly changed certain aspects of the United States patent laws, some of which are in effect on September 16, 2012 and others that will become effective March 16, 2013. These changes include, but are not limited to, authorizing fee setting authority to the United States Patent Office, transitioning the United States to a first-inventor-to file patent system, expanding the scope of prior art that may be utilized against a pending patent application, and adding post-patent grant proceedings before the Patent Office in which third parties may challenge the validity of the granted patent. Accordingly, it is not clear, what, if any, impact the AIA 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 or granted United States patents. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

---

## Table of Contents

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 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.

---

## Table of Contents

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.

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.

***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 rely on third parties, including clinical research organizations, or CROs, medical institutions and contract laboratories, to perform critical services for us in connection with our clinical trials. These third parties 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 established by the FDA and foreign regulatory authorities, which govern the conduct, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that trial subjects are adequately informed of the potential risks associated with participating in clinical trials. Our reliance on third parties does not relieve us of the responsibility to ensure these requirements are met. 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 good clinical practice regulations, our clinical trials may not meet regulatory requirements or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the product candidate being tested in such trials. 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.



---

## Table of Contents

***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 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.

---

## Table of Contents

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

Our investment securities consist of auction rate securities, corporate debt securities and government agency securities. As of September 30, 2012, our long-term investments included a (at par value) \$2.5 million auction rate security secured by municipal bonds. At September 30, 2012, the auction rate security we held maintained a Standard and Poor's credit rating of BBB. Our auction rate security is a debt instrument with a long-term maturity and with an interest rate that is reset in short intervals through auctions. The 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 our auction rate security held at September 30, 2012. As a result, this security is currently not liquid, and we could be required to hold it until it is redeemed by the issuer or to maturity. As of September 30, 2012, we had recognized \$0.5 million of losses related to the auction rate security by adjusting its carrying value. The market value of the security has partially recovered from the lows that created the losses. As of September 30, 2012, we had recorded cumulative unrealized gains of \$0.4 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 this investment is successful or it is redeemed by the issuer or it matures. If we are unable to sell this security in the market or it is not redeemed, then we may be required to hold it 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, 2009, to September 30, 2012, our stock price has ranged from \$1.20 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

## Table of Contents

- 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 currently have on file shelf registration statements that allow us to raise up to an aggregate of \$203.4 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.

## **ITEM 5. OTHER INFORMATION**

On November 7, 2012, we entered into an At-The-Market Equity Offering Sales Agreement with Stifel, Nicolaus & Company, Incorporated, or Stifel, under which we may issue and sell up to \$50,000,000 of shares of our common stock from time to time. Under the Sales Agreement, we will set the parameters for the sale of shares, including the number of shares to be issued and any minimum price below which sales may not be made. Subject to the terms and conditions of the Sales Agreement, shares may be sold through Stifel acting as sales agent or directly to Stifel acting as principal, by means of ordinary brokers' transactions on the NASDAQ Global Market, in privately negotiated transactions or otherwise at market prices prevailing at the time of sale, at prices related to prevailing market prices or at negotiated prices. Any sales other than by methods deemed to be an "at the market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act, will require our prior consent. Stifel is obligated to use commercially reasonable efforts in conducting sales activities. The Sales Agreement may be terminated by us upon prior notice to Stifel or by Stifel upon prior notice to us, or at any time under certain circumstances, including but not limited to the occurrence of a material adverse change in our company.

The Sales Agreement provides that Stifel will be entitled to compensation for its services in an amount of 2.5% of the gross proceeds from the sale of shares sold through Stifel under the Sales Agreement. We have no obligation to sell any shares under the Sales Agreement, and may at any time suspend offers under the Sales Agreement. We have agreed in the Sales Agreement to provide indemnification and contribution to Stifel against certain liabilities, including liabilities under the Securities Act, and to reimburse Stifel for certain legal expenses incurred in connection with the Sales Agreement.

The legal opinion of Cooley LLP relating to the shares of common stock being offered pursuant to the Sales Agreement is filed as Exhibit 5.1 to this Quarterly Report on Form 10-Q.



---

## Table of Contents

### **ITEM 6. EXHIBITS**

<b><u>Exhibit Number</u></b>	<b><u>Description of Document</u></b>
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.
5.1	Opinion of Cooley LLP.
10.1	At-The-Market Equity Offering Sales Agreement dated November 7, 2012 between the Company and Stifel, Nicolaus & Company, Incorporated.
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.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase.
(1)	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.
(2)	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.
*	Furnished herewith and not "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

---

## Table of Contents

### 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 7, 2012

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)

Sean M. Clayton  
T: +1 858 550 6034  
sclayton@cooley.com

November 7, 2012

Vical Incorporated  
10390 Pacific Center Court  
San Diego, CA 92121

Ladies and Gentlemen:

You have requested our opinion with respect to certain matters in connection with the offering by Vical Incorporated, a Delaware corporation (the “**Company**”), of the lesser of (i) \$50,000,000 of shares or (ii) 30,000,000 shares of the Company’s common stock, par value \$0.01 (the “**Shares**”), pursuant to a Registration Statement on Form S-3 (No. 333-181157) (the “**Registration Statement**”), filed with the Securities and Exchange Commission (the “**Commission**”) under the Securities Act of 1933, as amended (the “**Act**”), the prospectus included within the Registration Statement (the “**Base Prospectus**”), and the prospectus supplement dated November 7, 2012, filed with the Commission pursuant to Rule 424(b) of the Rules and Regulations of the Act (the “**Prospectus Supplement**” and together with the Base Prospectus, the “**Prospectus**”). The Shares are to be sold by the Company in accordance with the Sales Agreement, dated November 7, 2012, between the Company and Stifel, Nicolaus & Company, Incorporated (the “**Agreement**”), as described in the Prospectus.

In connection with this opinion, we have examined and relied upon the Registration Statement and the Prospectus, the Agreement, the Company’s Restated Certificate of Incorporation and Amended and Restated Bylaws, and the originals or copies certified to our satisfaction of such records, documents, certificates, memoranda and other instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below. In rendering this opinion, we have assumed the genuineness and authenticity of all signatures on original documents; the genuineness and authenticity of all documents submitted to us as originals; the conformity to originals of all documents submitted to us as copies; the accuracy, completeness and authenticity of certificates of public officials; and the due authorization, execution and delivery of all documents where due authorization, execution and delivery are prerequisites to the effectiveness of such documents.

Our opinion herein is expressed solely with respect to the federal laws of the United States of America and the General Corporation Law of the State of Delaware. Our opinion is based on these laws as in effect on the date hereof. We express no opinion as to whether the laws of any particular jurisdiction other than those identified above are applicable to the subject matter hereof.

On the basis of the foregoing, and in reliance thereon, we are of the opinion that the Shares, when sold and issued against payment therefor in accordance with the Agreement, the Registration Statement and the Prospectus, will be validly issued, fully paid and nonassessable.

4401 EASTGATE MALL, SAN DIEGO, CA 92121 T: (858) 550-6000 F: (858) 550-6420 WWW.COOLEY.COM

---

Vical Incorporated  
November 7, 2012  
Page Two

We consent to the reference to our firm under the caption “Legal Matters” in the Prospectus and to the filing of this opinion as an exhibit to a Quarterly Report on Form 10-Q to be filed with the Commission for incorporation by reference into the Registration Statement.

Very truly yours,

Cooley LLP

By: /s/ Sean M. Clayton  
Sean M. Clayton

4401 EASTGATE MALL, SAN DIEGO, CA 92121 T: (858) 550-6000 F: (858) 550-6420 WWW.COOLEY.COM

## VICAL INCORPORATED

Common Stock  
(\$0.01 par value per share)

## AT-THE-MARKET EQUITY OFFERING SALES AGREEMENT

November 7, 2012

STIFEL, NICOLAUS & COMPANY, INCORPORATED  
One South Street, 15<sup>th</sup> Floor  
Baltimore, Maryland 21202

Ladies and Gentlemen:

Vical Incorporated, a Delaware corporation (the “Company”), proposes, subject to the terms and conditions stated herein, to issue and sell from time to time to or through Stifel, Nicolaus & Company, Incorporated (“Stifel Nicolaus”), as sales agent and/or principal (“Agent”), shares (the “Shares”) of the Company’s common stock, \$0.01 par value per share (the “Common Stock”), having an aggregate offering price of up to \$50,000,000 (the “Maximum Offering Size”) on the terms set forth in Section 2 of this At-the-Market Equity Offering Sales Agreement (the “Agreement”). The Company agrees that whenever it determines to sell Shares directly to the Agent as principal, it will enter into a separate agreement (each, a “Terms Agreement”) in substantially the form of Annex I hereto, relating to such sale in accordance with Section 3 of this Agreement. The foregoing notwithstanding, the Company shall not issue or sell pursuant to this Agreement an aggregate amount of Common Stock that would cause the Company to exceed the amount of securities issuable pursuant to Instruction 1.B.6 of Form S-3 at any time the Company is subject to such limitation. For purposes of clarification, Stifel Nicolaus shall have no obligation with respect to the Company’s compliance with the foregoing sentence.

Section 1. Representations and Warranties. The Company represents and warrants to the Agent that as of the date of this Agreement, each Applicable Time (as defined in Section 1(c) below) and each Settlement Date (as defined in Section 2(g) below):

(a) Compliance with Registration Requirements. The Company has filed with the Securities and Exchange Commission (the “Commission”) a registration statement under the Securities Act of 1933, as amended (the “1933 Act”), on Form S-3 (File No. 333-181157), in respect of the Company’s Common Stock (including the Shares) (collectively, the “Securities”) not earlier than three years prior to the date hereof; such registration statement, and any post-effective amendment thereto, has become effective; and no stop order suspending the effectiveness of such registration statement or any part thereof has been issued and no proceeding for that purpose has been initiated or, to the knowledge of the Company, threatened by the Commission (the base prospectus filed as part of such registration statement, in the form in which it has most recently been filed with the Commission on or prior to the date of this Agreement, is hereinafter called the “Basic Prospectus”; the various parts of such registration statement, including all exhibits thereto and any prospectus supplement or prospectus relating to the Shares that is filed with the Commission and deemed by virtue of Rule 430B under the 1933 Act to be part of such registration statement, each as amended at the time such part of the registration statement became effective, are hereinafter collectively called the “Registration Statement”; the prospectus supplement specifically relating to the Shares prepared and filed with the Commission pursuant to Rule 424(b) under the 1933 Act is hereinafter called the “Prospectus Supplement”; the Basic Prospectus, as amended and supplemented by the Prospectus Supplement, is hereinafter called the “Prospectus”; any reference herein to the Basic Prospectus, the Prospectus Supplement or the Prospectus shall be deemed to refer to and include the documents incorporated by reference therein pursuant to Item 12 of Form S-3 under the 1933 Act; any reference to any amendment or supplement to the Basic Prospectus, the Prospectus Supplement or the Prospectus shall be deemed to refer to and include any post-effective amendment to the Registration Statement, any prospectus supplement or prospectus relating to the Shares filed with the Commission pursuant to Rule 424(b) under the 1933 Act and any documents filed under the Securities Exchange Act of 1934, as amended (the “1934 Act”), and incorporated therein, in each case after the date of the Basic Prospectus, the Prospectus Supplement or the Prospectus, as the case may be; any reference to any amendment to

the Registration Statement shall be deemed to refer to and include any annual report of the Company filed pursuant to Section 13(a) or 15(d) of the 1934 Act after the effective date of the Registration Statement that is incorporated by reference in the Registration Statement; and any “issuer free writing prospectus” as defined in Rule 433 under the 1933 Act relating to the Shares is hereinafter called an “Issuer Free Writing Prospectus”).

No order preventing or suspending the use of the Basic Prospectus, the Prospectus Supplement, the Prospectus or any Issuer Free Writing Prospectus has been issued by the Commission, and the Basic Prospectus and the Prospectus Supplement, at the time of filing thereof, conformed in all material respects to the requirements of the 1933 Act and the rules and regulations of the Commission thereunder (the “1933 Act Regulations”) and did not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

For the purposes of this Agreement, the “Applicable Time” means, with respect to any Shares, the time of delivery of instructions to sell Shares pursuant to Section 2(b) hereof or of delivery of a Terms Agreement, as applicable, for the sale of such Shares pursuant to this Agreement. The Prospectus and the applicable Issuer Free Writing Prospectus(es) issued at or prior to such Applicable Time, taken together (collectively, and, with respect to any Shares, together with the public offering price of such Shares, the “General Disclosure Package”) as of each Applicable Time and each Settlement Date, will not include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; and each applicable Issuer Free Writing Prospectus will not conflict with the information contained in the Registration Statement, the Prospectus Supplement or the Prospectus and each such Issuer Free Writing Prospectus, as supplemented by and taken together with the General Disclosure Package as of such Applicable Time, will not include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(b) Incorporation of Documents by Reference. The documents incorporated or deemed to be incorporated by reference in the Registration Statement and the Prospectus, when they became effective or were filed with the Commission, as the case may be, complied in all material respects with the requirements of the 1934 Act and the rules and regulations of the Commission under the 1934 Act, and, when read together with the other information in the Prospectus, (a) at the time the Registration Statement became effective, (b) at the time the Prospectus was issued and (c) on the date of this Agreement, did not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(c) Independent Registered Public Accounting Firm. Ernst & Young LLP, who have expressed their opinion with respect to the financial statements (which term as used in this Agreement includes the related notes thereto) filed with the Commission as a part of the Registration Statement and incorporated by reference in the General Disclosure Package and the Prospectus (each, an “Applicable Prospectus” and collectively, the “Applicable Prospectuses”), are (i) independent public or certified public accountants as required by the 1933 Act and the 1934 Act, (ii) in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X and (iii) an independent registered public accounting firm as defined by the Public Company Accounting Oversight Board (the “PCAOB”) whose registration has not been suspended or revoked and, to the Company’s knowledge, who has not requested such registration to be withdrawn.

(d) Financial Statements. The financial statements filed with the Commission as a part of the Registration Statement and included in the General Disclosure Package and the Prospectus present fairly the consolidated financial position of the Company and its subsidiaries as of and at the dates indicated and the results of their operations and cash flows for the periods specified. The supporting schedules included in the Registration Statement present fairly the information required to be stated therein. Such financial statements and supporting schedules have been prepared in conformity with generally accepted accounting principles as applied in the United States applied on a consistent basis throughout the periods involved, except as may be expressly stated in the related notes thereto. No other financial statements or supporting schedules are required to be included in a Registration Statement or any Applicable Prospectus. The financial data set forth or incorporated by reference in each Applicable Prospectus fairly present the information set forth therein on a basis consistent with that of the audited

financial statements contained in each Registration Statement and each Applicable Prospectus. To the Company's knowledge, no person who has been suspended or barred from being associated with a registered public accounting firm, or who has failed to comply with any sanction pursuant to Rule 5300 promulgated by the PCAOB, has participated in or otherwise aided the preparation of, or audited, the financial statements, supporting schedules or other financial data filed with the Commission as a part of a Registration Statement and included in any Applicable Prospectus.

(e) No Material Adverse Change in Business. Except as otherwise disclosed in the General Disclosure Package, subsequent to the respective dates as of which information is given in the General Disclosure Package: (i) there has been no material adverse change, or any development that could reasonably be expected to result in a material adverse change, in the condition, financial or otherwise, or in the earnings, business, operations or prospects, whether or not arising from transactions in the ordinary course of business, of the Company and its subsidiaries, considered as one entity (any such change is called a "Material Adverse Change"); (ii) the Company and its subsidiaries, considered as one entity, have not incurred any material liability or obligation, indirect, direct or contingent, not in the ordinary course of business nor entered into any material transaction or agreement not in the ordinary course of business; and (iii) there has been no dividend or distribution of any kind declared, paid or made by the Company or, except for dividends paid to the Company or other subsidiaries, any of its subsidiaries on any class of capital stock or repurchase or redemption by the Company or any of its subsidiaries of any class of capital stock.

(f) Incorporation and Good Standing of the Company and its Subsidiaries. Each of the Company and its subsidiaries has been duly incorporated or organized, as the case may be, and is validly existing as a corporation, partnership or limited liability company, as applicable, in good standing under the laws of the jurisdiction of its incorporation or organization and has the power and authority (corporate or other) to own, lease and operate its properties and to conduct its business as described in each Applicable Prospectus and, in the case of the Company, to enter into and perform its obligations under this Agreement, except where the failure to be in good standing would not reasonably be expected to result in a Material Adverse Change. Each of the Company and each subsidiary is duly qualified as a foreign corporation, partnership or limited liability company, as applicable, to transact business and is in good standing in the State of California and each other jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure to be so qualified or in good standing would not reasonably be expected to result in a Material Adverse Change. All of the issued and outstanding capital stock or other equity or ownership interests of each subsidiary have been duly authorized and validly issued, are fully paid and nonassessable and, except as set forth in the General Disclosure Package, are owned by the Company, directly or through subsidiaries, free and clear of any security interest, mortgage, pledge, lien, encumbrance or adverse claim. The Company does not own or control, directly or indirectly, any corporation, association or other entity other than (i) the subsidiaries, if any, listed in Exhibit 21 to the Company's most recent Annual Report on Form 10 K, (ii) any subsidiaries described in the General Disclosure Package and (iii) such other entities omitted from Exhibit 21 which, when such omitted entities are considered in the aggregate as a single subsidiary, would not constitute a "significant subsidiary" within the meaning of Rule 1-02(w) of Regulation S-X.

(g) Capitalization and Other Capital Stock Matters. As of the dates indicated therein, the authorized, issued and outstanding capital stock of the Company was as set forth in each Applicable Prospectus. Since the most recent date such information was included in an Applicable Prospectus, there has been no material change in the authorized, issued and outstanding capital stock of the Company (other than for subsequent issuances, if any, pursuant to employee benefit plans described in such General Disclosure Package, upon the exercise of outstanding options or warrants or the settlement of restricted stock units described in such Applicable Prospectus, as a result of sales of Shares hereunder or as otherwise described in the General Disclosure Package). The shares of Common Stock (including the Shares) conform in all material respects to the description thereof contained in the General Disclosure Package. All of the issued and outstanding Shares have been duly authorized and validly issued, are fully paid and nonassessable and have been issued in compliance with federal and state securities laws. None of the outstanding Shares was issued in violation of any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities of the Company. Except as may have been issued pursuant to the Company's stock option and other stock plans or arrangements, in each case as described in the General Disclosure Package, there are no authorized or outstanding options, warrants, preemptive rights, rights of first refusal or other rights to purchase, or equity or debt securities convertible into or exchangeable or exercisable for, any capital stock of the

Company or any of its subsidiaries other than those accurately described in each Applicable Prospectus. The description of the Company's stock option, stock bonus and other stock plans or arrangements, and the options or other rights granted thereunder, set forth in each Applicable Prospectus accurately and fairly presents the information required to be shown with respect to such plans, arrangements, options and rights. All grants of options to acquire shares of Common Stock (each, a "Company Stock Option") were validly issued and approved by the Board of Directors of the Company, a committee thereof or an individual with authority duly delegated by the Board of Directors of the Company or a committee thereof. Grants of Company Stock Options were (i) made in material compliance with all applicable laws and (ii) as a whole, made in material compliance with the terms of the plans under which such Company Stock Options were issued. There is no and has been no policy or practice of the Company to coordinate the grant of Company Stock Options with the release or other public announcement of material information regarding the Company or its results of operations or prospects. Except as described in the General Disclosure Package and the Prospectus, the Company has not sold or issued any Shares during the six-month period preceding the date of any Prospectus, including any sales pursuant to Rule 144A under, or Regulations D or S of, the 1933 Act other than Shares issued pursuant to employee benefit plans, qualified stock options plans or other employee compensation plans or pursuant to outstanding options, rights or warrants.

(h) Authorization of Agreements. This Agreement has been, and any Terms Agreement will be, duly authorized, executed and delivered by, and this Agreement is, and any Terms Agreement will be, a valid and binding agreement of, the Company, enforceable against the Company in accordance with its terms, except as rights to indemnification hereunder may be limited by applicable law and except as the enforcement hereof may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar laws relating to or affecting the rights and remedies of creditors or by general equitable principles.

(i) Authorization of Shares. The Shares have been duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by the Company pursuant to this Agreement or any Terms Agreement, will be validly issued, fully paid and nonassessable, and the issuance and sale of the Shares is not subject to any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase the Shares.

(j) Non-Contravention of Existing Instruments; No Further Authorizations or Approvals Required. Neither the Company nor any of its subsidiaries is in violation of its charter or bylaws, partnership agreement or operating agreement or similar organizational document, as applicable, or is in default (or, with the giving of notice or lapse of time, would be in default) ("Default") under any indenture, mortgage, loan or credit agreement, note, contract, franchise, lease or other instrument to which the Company or any of its subsidiaries is a party or by which it or any of them may be bound (including, without limitation, any credit agreement, indenture, pledge agreement, security agreement or other instrument or agreement evidencing, guaranteeing, securing or relating to indebtedness of the Company or any of its subsidiaries), or to which any of the property or assets of the Company or any of its subsidiaries is subject (each, an "Existing Instrument"), except for such Defaults described in the General Disclosure Package or as would not reasonably be expected to, individually or in the aggregate, result in a Material Adverse Change. The Company's execution, delivery and performance of this Agreement and any Terms Agreement, consummation of the transactions contemplated hereby and by any Terms Agreement and by each Applicable Prospectus and the issuance and sale of the Shares (i) have been duly authorized by all necessary corporate action and will not result in any violation of the provisions of the charter or bylaws, partnership agreement or operating agreement or similar organizational document of the Company or any subsidiary, as applicable, (ii) will not conflict with or constitute a breach of, or Default under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company or any of its subsidiaries pursuant to, or require the consent of any other party to, any Existing Instrument, except for such breaches, Defaults or results, or failure to obtain such consent, as would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change and (iii) will not result in any violation of any law, administrative regulation or administrative or court decree applicable to the Company or any subsidiary, except for such violations as would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change. No consent, approval, authorization or other order of, or registration or filing with, any court or other governmental or regulatory authority or agency, is required for the Company's execution, delivery and performance of this Agreement or any Terms Agreement and consummation of the transactions contemplated hereby and by any Terms Agreement and each Applicable Prospectus, except such as have been obtained or made or will be made by the Company under the 1933 Act, or that may be required under applicable state securities or blue sky laws and from the Financial Industry Regulatory Authority ("FINRA").



(k) No Material Actions or Proceedings. Except as disclosed in the General Disclosure Package, there are no legal or governmental actions, suits or proceedings pending or, to the Company's knowledge, threatened against or affecting the Company or any of its subsidiaries, which (i) have as the subject thereof any officer or director of, or property owned or leased by, the Company or any of its subsidiaries or (ii) relate to environmental or discrimination matters, where in any such case (A) to the Company's knowledge, there is a substantial likelihood that such action, suit or proceeding will be determined adversely to the Company, such subsidiary or such officer or director, (B) any such action, suit or proceeding, if so determined adversely, would reasonably be expected to result in a Material Adverse Change or adversely affect the consummation of the transactions contemplated by this Agreement or (C) any such action, suit or proceeding is or would be material in the context of the sale of Shares. Except as disclosed in the General Disclosure Package, no material labor dispute with the employees of the Company or any of its subsidiaries, or to the Company's knowledge, with the employees of any principal supplier, manufacturer, customer or contractor of the Company, exists or, to the Company's knowledge, is threatened or imminent.

(l) Accuracy of Exhibits. There are no contracts or documents which are required to be described in the Registration Statement or the Prospectus or the documents incorporated by reference therein or to be filed as exhibits thereto which have not been so described and filed as required.

(m) Intellectual Property Rights. Except as disclosed in the General Disclosure Package, the Company and its subsidiaries own, possess or can acquire on reasonable terms sufficient trademarks, trade names, patent rights, copyrights, domain names, licenses, approvals, trade secrets and other similar rights (collectively, "Intellectual Property Rights") reasonably necessary to conduct their businesses as now conducted; except to the extent failure to own, possess or acquire such Intellectual Property Rights would not result in a Material Adverse Change. Except as disclosed in the General Disclosure Package, neither the Company nor any of its subsidiaries has received, or has any reason to believe that it will receive, any notice of infringement or conflict with asserted Intellectual Property Rights of others. Except as disclosed in the General Disclosure Package or as would not be reasonably likely to result, individually or in the aggregate, in a Material Adverse Change, (A) to the Company's knowledge, there is no infringement, misappropriation or violation by third parties of any of the Intellectual Property Rights owned by the Company; (B) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the rights of the Company and its subsidiaries in or to any such Intellectual Property Rights, and the Company is unaware of any facts which would form a reasonable basis for any such claim, that would, individually or in the aggregate, together with any other claims in this subsection (m) result in a Material Adverse Change; (C) the Intellectual Property Rights owned by the Company and its subsidiaries and, to the Company's knowledge, the Intellectual Property Rights licensed to the Company and its subsidiaries have not been adjudged by a court of competent jurisdiction invalid or unenforceable, in whole or in part, and except as otherwise disclosed in the General Disclosure Package, there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the validity or scope of any such Intellectual Property Rights, and the Company is unaware of any facts which would form a reasonable basis for any such claim that would, individually or in the aggregate, together with any other claims in this subsection (m) result in a Material Adverse Change; (D) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others that the Company or its subsidiaries infringe, misappropriate or otherwise violate any Intellectual Property Rights or other proprietary rights of others, the Company and its subsidiaries have not received any written notice of such claim and the Company is unaware of any other facts which would form a reasonable basis for any such claim that would reasonably be expected, individually or in the aggregate, together with any other claims in this subsection (m) to result in a Material Adverse Change; and (E) to the Company's knowledge, no employee of the Company or a subsidiary of the Company is in or has ever been in violation in any material respect of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee's employment with the Company or a subsidiary of the Company, or actions undertaken by the employee while employed with the Company or a subsidiary of the Company and would reasonably be expected to result, individually or in the aggregate, in a Material Adverse Change. To the Company's knowledge, all material technical information developed by and belonging to the Company and its subsidiaries for which they have not sought, and do not intend to seek, to patent or otherwise protect pursuant to applicable intellectual property laws has been kept confidential or disclosed only under obligations of confidentiality. The Company is not a party to or bound by any options, licenses or agreements with

respect to the Intellectual Property Rights of any other person or entity that are required to be set forth in any Applicable Prospectus and are not described therein. The General Disclosure Package contains in all material respects the same description of the matters set forth in the preceding sentence contained in any Applicable Prospectus. None of the technology employed by the Company or any of its subsidiaries has been obtained or is being used by the Company or any of its subsidiaries in violation of any contractual obligation binding on the Company or any of its subsidiaries or, to the Company's knowledge, any of its or its subsidiaries' officers, directors or employees or otherwise in violation of the rights of any persons, except in each case for such violations that would not reasonably be expected to result in a Material Adverse Change.

(n) No Price Stabilization or Manipulation; Compliance with Regulation M. The Company has not taken, nor will the Company take, directly or indirectly, any action designed to or that might be reasonably expected to cause or result in stabilization or manipulation of the price of the shares of Common Stock or any other "reference security" (as defined in Rule 100 of Regulation M under the 1934 Act (" Regulation M ")) whether to facilitate the sale or resale of the Shares or otherwise, and has taken no action which would directly or indirectly violate Regulation M.

(o) All Necessary Permits. Except as disclosed in the General Disclosure Package, the Company and each subsidiary possess such valid and current certificates, authorizations, approvals, exemptions and/or permits issued by the appropriate state, federal or foreign regulatory agencies or bodies necessary to conduct their respective businesses, and neither the Company nor any subsidiary has received, or has any reason to believe that it will receive, any notice of proceedings relating to the revocation or modification of, or non-compliance with, any such certificate, authorization or permit which, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would reasonably be expected to result in a Material Adverse Change.

(p) Title to Property. The Company and each of its subsidiaries has good and marketable title to all of the real and personal property and other assets reflected as owned in the financial statements referred to in Section 1(d) above (or elsewhere in any Applicable Prospectus), in each case free and clear of any security interests, mortgages, liens, encumbrances, equities, adverse claims and other defects, except such as do not materially and adversely affect the value of such property and do not materially interfere with the use made or proposed to be made of such property by the Company or such subsidiary. To the Company's knowledge, the real property, improvements, equipment and personal property held under lease by the Company or any subsidiary are held under valid and enforceable leases, with such exceptions as are not material and do not materially interfere with the use made or proposed to be made of such real property, improvements, equipment or personal property by the Company or such subsidiary.

(q) Company Not an "Investment Company". The Company is not and, after giving effect to the offering and sale of the Shares and the application of the proceeds therefrom as described under "Use of Proceeds" in each Applicable Prospectus, will not be required to register as an "investment company," as such term is defined in the Investment Company Act of 1940, as amended, and will not be an entity "controlled" by an "investment company" within the meaning of such Act.

(r) Compliance with Environmental Laws. Except as described in each Applicable Prospectus and except as would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Change, (i) neither the Company nor any of its subsidiaries is in violation of any federal, state, local or foreign statute, law, rule, regulation, ordinance, code, policy or rule of common law or any judicial or administrative interpretation thereof, including any judicial or administrative order, consent, decree or judgment, relating to pollution or protection of human health, the environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata) or wildlife, including, without limitation, laws and regulations relating to the release or threatened release of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum or petroleum products (collectively, " Hazardous Materials ") or to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials (collectively, " Environmental Laws "), (ii) the Company and its subsidiaries have all permits, authorizations and approvals required under any applicable Environmental Laws and are each in compliance with their requirements, (iii) there are no pending or, to the Company's knowledge, threatened administrative, regulatory or judicial actions, suits, demands, demand letters, claims, liens, notices of noncompliance or violation, investigation or proceedings relating to any Environmental Law against the Company or any of its subsidiaries and (iv) there are no events or circumstances of which the Company

is aware that might reasonably be expected to form the basis of an order for clean-up or remediation, or an action, suit or proceeding by any private party or governmental body or agency, against or affecting the Company or any of its subsidiaries relating to Hazardous Materials or any Environmental Laws.

(s) No Applicable Registration or Other Similar Rights. There are no persons with registration or other similar rights to have any equity or debt securities registered for sale under a Registration Statement or included in the offering contemplated by this Agreement, except for such rights as have been duly waived.

(t) Company's Accounting System. The Company and each of its subsidiaries make and keep accurate books and records and maintain a system of internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles as applied in the United States and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Except as disclosed in the General Disclosure Package, the Company is not aware of any material weakness in the Company's internal control over financial reporting (whether or not remediated) and since the most recent fiscal year-end, there has been no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

(u) S-3 Eligibility. At the time the Registration Statement was originally declared effective and at the time the Company's Annual Report on Form 10-K for the year ended December 31, 2011 (the "Annual Report") was filed with the Commission, the Company met the then applicable requirements for use of Form S-3 under the 1933 Act. The Company is eligible to offer and sell securities under the Registration Statement (including the offer and sale of the Shares). At the earliest time after the filing of the Registration Statement that the Company or another offering participant made a bona fide offer (within the meaning of Rule 164(h)(2) under the 1933 Act) of the Shares, the Company was not an "ineligible issuer" as defined in Rule 405 under the 1933 Act.

(v) Brokers. Except as contemplated by this Agreement or any Terms Agreement, there is no broker, finder or other party that is entitled to receive from the Company any brokerage or finder's fee or other fee or commission as a result of any transactions contemplated by this Agreement or any Terms Agreement.

(w) [Reserved].

(x) Deemed Representation. Any certificate signed by any officer of the Company delivered to the Agent or to counsel for the Agent pursuant to or in connection with this Agreement or any Terms Agreement shall be deemed a representation and warranty by the Company to the Agent as to the matters covered thereby as of the date or dates indicated in such certificate.

(y) Compliance with the Sarbanes-Oxley Act. There is and has been no failure on the part of the Company and any of the Company's directors or officers, in their capacities as such, to comply with any provision of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith, including Section 402 relating to loans and Sections 302 and 906 relating to certifications.

(z) Tax Law Compliance. The Company and its consolidated subsidiaries have timely filed all federal, state and foreign income and franchise tax returns required to be filed or have obtained extensions thereof and have timely paid all taxes (including, without limitation, any estimated taxes) required to be paid by any of them and, if due and payable, any related or similar assessment, fine or penalty levied against any of them except as may be being contested in good faith and by appropriate proceedings. The Company has made adequate charges, accruals and reserves in the applicable financial statements referred to in Section 1(d) above in respect of all federal, state and foreign income and franchise taxes for all periods as to which the tax liability of the Company or any of its consolidated subsidiaries has not been finally determined.

(aa) Insurance. Each of the Company and its subsidiaries are insured by recognized, financially sound and reputable institutions with policies in such amounts and with such deductibles and covering such risks as are generally deemed adequate and customary for their businesses including, but not limited to, policies covering real and personal property owned or leased by the Company and its subsidiaries against theft, damage, destruction and acts of vandalism and policies covering the Company and its subsidiaries for product liability claims and clinical trial liability claims. The Company has no reason to believe that it or any subsidiary will not be able (i) to renew its existing insurance coverage as and when such policies expire or (ii) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not result in a Material Adverse Change. During the past three years, the Company has not been denied any insurance coverage material to the Company which it has sought or for which it has applied.

(bb) Statistical and Market-Related Data. The statistical, demographic and market-related data included in each Registration Statement and each Applicable Prospectus are based on or derived from sources that the Company believes to be reliable and accurate or represent the Company's good faith estimates that are made on the basis of data derived from such sources.

(cc) No Unlawful Contributions or Other Payments. Neither the Company nor any of its subsidiaries nor, to the Company's knowledge, any employee or agent of the Company or any subsidiary, has made any contribution or other payment to any official of, or candidate for, any federal, state or foreign office in violation of any law or of the character required to be disclosed in each Registration Statement and each Applicable Prospectus.

(dd) Disclosure Controls and Procedures; Deficiencies in or Changes to Internal Control Over Financial Reporting. The Company has established and maintains disclosure controls and procedures (as defined in 1934 Act Rules 13a-15(e) and 15d-15(e)), which (i) are designed to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to the Company's principal executive officer and its principal financial officer by others within those entities, particularly during the periods in which the periodic reports required under the 1934 Act are being prepared; (ii) have been evaluated by management of the Company for effectiveness as of the end of the Company's most recent fiscal quarter; and (iii) the Company's principal executive officer and principal financial officer concluded to be effective at the reasonable assurance level. Based on the most recent evaluation of its disclosure controls and procedures, except as disclosed in the General Disclosure Package, the Company is not aware of (i) any significant deficiencies or material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information or (ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting. The Company is not aware of any change in its internal control over financial reporting that has occurred during its most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

(ee) Stock Exchange Listing. The shares of Common Stock are registered pursuant to Section 12(b) of the 1934 Act and are listed on the Nasdaq Global Market, and the Company has taken no action designed to, or likely to have the effect of, terminating the registration of the shares of Common Stock under the 1934 Act or delisting the shares from the Nasdaq Global Market, nor has the Company received any notification that the Commission or the Nasdaq Global Market is contemplating terminating such registration or listing.

(ff) Related Party Transactions. There are no business relationships or related-party transactions involving the Company or any of its subsidiaries or any other person required to be described in each Applicable Prospectus which have not been described as required. The General Disclosure Package contains in all material respects the same description of the matters set forth in the preceding sentence contained in each Applicable Prospectus.

(gg) FINRA Matters. All of the information provided to the Agent or to counsel for the Agent by the Company, its officers and directors and the holders of any securities (debt or equity) or options to acquire any

securities of the Company in connection with letters, filings or other supplemental information provided to FINRA pursuant to FINRA Rule 5110 or the National Association of Securities Dealers Inc. (the “NASD”) Conduct Rule 2710 or 2720 is true, complete and correct. Neither the Company nor, to the knowledge of the Company, any of its affiliates (within the meaning of the NASD Conduct Rule 2720(f)(1)) directly or indirectly controls, is controlled by, or is under common control with, or is an associated person (within the meaning of Article I Section 1(ee) of the By-laws of FINRA) of, any member of FINRA. To the Company’s knowledge, there are no affiliations with FINRA among the Company’s officers or directors.

(hh) ERISA Compliance. The Company and its subsidiaries and any “employee benefit plan” (as defined under the Employee Retirement Income Security Act of 1974, as amended, and the regulations and published interpretations thereunder (collectively, “ERISA”)) established or maintained by the Company, its subsidiaries or their “ERISA Affiliates” (as defined below) are in compliance in all material respects with ERISA. “ERISA Affiliate” means, with respect to the Company or a subsidiary, any member of any group of organizations described in Sections 414(b),(c),(m) or (o) of the Internal Revenue Code of 1986, as amended, and the regulations and published interpretations thereunder (the “Code”) of which the Company or such subsidiary is a member. Except as described in the General Disclosure Package, no “reportable event” (as defined under ERISA) has occurred or is reasonably expected to occur with respect to any “employee benefit plan” established or maintained by the Company, its subsidiaries or any of their ERISA Affiliates. Except as described in the General Disclosure Package, no “employee benefit plan” established or maintained by the Company, its subsidiaries or any of their ERISA Affiliates, if such “employee benefit plan” were terminated, would have any “amount of unfunded benefit liabilities” (as defined under ERISA). Except as described in the General Disclosure Package, neither the Company, its subsidiaries nor any of their ERISA Affiliates has incurred or reasonably expects to incur any liability under (i) Title IV of ERISA with respect to termination of, or withdrawal from, any “employee benefit plan” or (ii) Sections 412, 4971, 4975 or 4980B of the Code. Each “employee benefit plan” established or maintained by the Company, its subsidiaries or any of their ERISA Affiliates that is intended to be qualified under Section 401(a) of the Code is so qualified and, except as described in the General Disclosure Package, nothing has occurred, whether by action or failure to act, which would reasonably be expected to result in the loss of such qualification.

(ii) No Outstanding Loans or Other Extensions of Credit. Except as described in the General Disclosure Package, since the adoption of Section 13(k) of the 1934 Act, neither the Company nor any of its subsidiaries has extended or maintained credit, arranged for the extension of credit, or renewed any extension of credit, in the form of a personal loan, to or for any director or executive officer (or equivalent thereof) of the Company and/or such subsidiary except for such extensions of credit as are expressly permitted by Section 13(k) of the 1934 Act.

(jj) Compliance with Laws. The Company has not been advised, and has no reason to believe, that it and each of its subsidiaries are not conducting business in compliance with all applicable laws, rules and regulations of the jurisdictions in which it is conducting business, except where failure to be so in compliance would not result in a Material Adverse Change. Except as described in the General Disclosure Package, the Company has not received any FDA Form 483, notice of adverse finding, warning letter, untitled letter or other correspondence or notice from the U.S. Food and Drug Administration or any other governmental authority alleging or asserting noncompliance with any laws applicable to the Company.

(kk) Clinical Trials. The studies, tests and preclinical and clinical trials conducted by or on behalf of the Company and its subsidiaries were and, if still pending, are being conducted in compliance with experimental protocols, procedures and controls pursuant to accepted professional scientific standards and all applicable laws and authorizations, including, without limitation, the Federal Food, Drug and Cosmetic Act and the rules and regulations promulgated thereunder, except where the failure to be in compliance has not resulted and would not reasonably be expected to result in a Material Adverse Change; the descriptions of the results of such studies, tests and trials contained in any Applicable Prospectus are accurate and complete in all material respects and fairly present the data derived from such studies, tests and trials; except to the extent disclosed in any Applicable Prospectus, the Company is not aware of any studies, tests or trials, the results of which the Company believes reasonably call into question the study, test, or trial results described or referred to in any Applicable Prospectus when viewed in the context in which such results are described and the clinical state of development; and the Company and its subsidiaries have not received any notices or correspondence from any applicable governmental authority requiring the termination, suspension or material modification of any studies, tests or preclinical or clinical trials conducted by or on behalf of the Company or its subsidiaries.

(ll) Dividend Restrictions. No subsidiary of the Company is prohibited or restricted, directly or indirectly, from paying dividends to the Company, or from making any other distribution with respect to such subsidiary's equity securities or from repaying to the Company or any other subsidiary of the Company any amounts that may from time to time become due under any loans or advances to such subsidiary from the Company or from transferring any property or assets to the Company or to any other subsidiary.

(mm) Foreign Corrupt Practices Act. Neither the Company nor any of its subsidiaries nor, to the Company's knowledge, any director, officer, agent, employee, affiliate or other person acting on behalf of the Company or any of its subsidiaries is aware of or has taken any action, directly or indirectly, that has resulted or would result in a violation of the Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (the "FCPA"), including, without limitation, making use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay or authorization of the payment of any money, or other property, gift, promise to give, or authorization of the giving of anything of value to any "foreign official" (as such term is defined in the FCPA) or any foreign political party or official thereof or any candidate for foreign political office, in contravention of the FCPA; and the Company and its subsidiaries and, to the Company's knowledge, the Company's affiliates have conducted their respective businesses in compliance with the FCPA and have instituted and maintain policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith.

(nn) Money Laundering Laws. The operations of the Company and its subsidiaries are, and have been conducted at all times, in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all applicable jurisdictions, the rules and regulations thereunder and any related or similar applicable rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "Money Laundering Laws") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending or, to the Company's knowledge, threatened.

(oo) OFAC. Neither the Company nor any of its subsidiaries nor, to the Company's knowledge, any director, officer, agent, employee, affiliate or person acting on behalf of the Company or any of its subsidiaries is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC"); and the Company will not directly or indirectly use the proceeds of this offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity, for the purpose of financing the activities of any person currently subject to any U.S. sanctions administered by OFAC.

(pp) FINRA Filing Exemption. To enable the Agent to rely on FINRA Rule 5110(b)(7)(C)(i), (i) the Company was subject to the requirements of Section 12 or 15(d) of the 1934 Act and filed all the material required to be filed pursuant to Sections 13, 14 or 15(d) for a period of at least thirty-six calendar months immediately preceding the date of this Agreement; (ii) the Company filed in a timely manner all reports required to be filed pursuant to Section 13, 14 or 15(d) of the 1934 Act during the twelve calendar months and any portion of a month immediately preceding the date of this Agreement; (iii) the last reported sale price of the Company's common stock on the Nasdaq Global Market on November 6, 2012 was \$3.44; (iv) as of such date, there were greater than 50,000,000 shares of the Company's common stock outstanding and held by non-affiliates of the Company; and (v) the Company has annual trading volume of 3 million shares or more.

(qq) Offering Materials Furnished to Agent. If so requested by the Agent, the Company will deliver to the Agent two complete copies of the Registration Statement, each amendment thereto and any Rule 462(b) Registration Statement and of each consent and certificate of experts filed as a part thereof.

(rr) Distribution of Offering Material By the Company. The Company has not distributed and will not distribute, prior to the completion of the Agent's distribution of the Shares, any offering material in connection with the offering and sale of the Shares pursuant to this Agreement other than the Basic Prospectus, the General Disclosure Package, the Prospectus, any free writing prospectus reviewed and consented to by the Agent, or the Registration Statement.

## Section 2. Sale and Delivery of Shares.

(a) Subject to the terms and conditions set forth herein, the Company agrees to issue and sell through the Agent acting as sales agent or directly to the Agent acting as principal from time to time, and the Agent agrees to use its commercially reasonable efforts to sell as sales agent for the Company, the Shares, up to the amounts that may be specified in any Terms Agreement or as otherwise specified by the Company pursuant to Section 2(b). Sales of the Shares, if any, through the Agent acting as sales agent or directly to the Agent acting as principal will be made by means of ordinary brokers' transactions on the Nasdaq Global Market, in privately negotiated transactions or otherwise at market prices prevailing at the time of sale, at prices related to prevailing market prices or at negotiated prices. Anything to the contrary notwithstanding in this Agreement, without the Company's prior written consent (which may include explicit authorization in a Terms Agreement), the Agent may not place Shares (a) by any method other than those deemed to be an "at the market" offering as defined in Rule 415 of the 1933 Act, including without limitation sales made through the Nasdaq Global Market, on any other existing trading market for the Common Stock or to or through a market maker, (b) in privately negotiated transactions, or (c) for its own account as principal. The Agent shall effect any sales of Shares in accordance with applicable state and federal laws, rules and regulations and the rules of the Nasdaq Stock Market and otherwise in accordance with the terms of the applicable Terms Agreement. Nothing contained herein restricts, nor may be deemed to restrict, the Company from undertaking another offering of its securities pursuant to a separate registration under the 1933 Act (or an exemption from such registration), or another offering under the Registration Statement, provided the Company complies with Section 3(p).

(b) Subject to the applicable Terms Agreement or instructions to sell shares delivered pursuant to this Section 2(b), the Shares to be sold pursuant to this Agreement are to be sold on a daily basis or otherwise as shall be agreed to by the Company and the Agent on that trading day (other than a day on which the Nasdaq Global Market is scheduled to close prior to its regular weekday closing time, each, a "Trading Day") that the Company has satisfied its obligations under Section 6 of this Agreement and that the Company has instructed the Agent to make such sales; provided that, so long as the Company's Common Stock is not an "actively-traded security" within the meaning of Rule 101(c)(1) of Regulation M, in connection with the Agent's initiation of research reports about the Company, the Agent may, in its reasonable discretion, by notice to the Company, delay the start of sales activity under this Agreement or any Terms Agreement by up to two Trading Days as is reasonably necessary to ensure compliance with Regulation M and any other applicable legal or regulatory requirements. On any Trading Day, the Company may instruct the Agent by telephone (confirmed promptly by telecopy or email, which confirmation will be promptly acknowledged by the Agent) as to the maximum number of Shares to be sold by the Agent on such day (in any event not in excess of the number available for issuance under the Prospectus and the currently effective Registration Statement) and the minimum price per Share at which such Shares may be sold. Subject to the terms and conditions hereof, the Agent shall use its commercially reasonable efforts to sell as sales agent all of the Shares so designated by the Company and in the manner and on the terms designated by the Company. The Company and the Agent each acknowledge and agree that (A) there can be no assurance that the Agent will be successful in selling the Shares, (B) the Agent will incur no liability or obligation to the Company or any other person or entity if they do not sell Shares for any reason other than a failure by the Agent to use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable law and regulations to sell such Shares as required by this Agreement, and (C) the Agent shall be under no obligation to purchase Shares on a principal basis except as otherwise specifically agreed by each of the Agent and the Company pursuant to a Terms Agreement. In the event of a conflict between the terms of this Agreement and the terms of a Terms Agreement, the terms of such Terms Agreement will control.

(c) Notwithstanding the foregoing, the Company shall not authorize the issuance and sale of, and the Agent as sales agent shall not be obligated to use its commercially reasonable efforts to sell, any Shares (i) at a price lower than the minimum price therefor authorized from time to time, or (ii) in a number in excess of the number of Shares authorized from time to time to be issued and sold under this Agreement, in each case, by the

Company's board of directors, or a duly authorized committee thereof, and notified to the Agent in writing. In addition, the Company may, upon notice to the Agent, suspend the offering of the Shares or the Agent may, upon notice to the Company, suspend the offering of the Shares with respect to which the Agent is acting as sales agent for any reason and at any time; provided, however, that such suspension or termination shall not affect or impair the parties' respective obligations with respect to the Shares sold hereunder prior to the giving of such notice. Any notice given pursuant to the preceding sentence may be given by telephone (confirmed promptly by telecopy or email, which confirmation will be promptly acknowledged).

(d) The gross sales price of any Shares sold pursuant to this Agreement by the Agent acting as sales agent of the Company shall be the market price prevailing at the time of sale for shares of the Company's Common Stock sold by the Agent on the Nasdaq Global Market or other existing trading market for the Common Stock, or, if agreed to by the Company, at prices relating to prevailing market prices or at negotiated prices. The compensation payable to the Agent for sales of Shares with respect to which the Agent acts as sales agent shall be equal to 2.5% of the gross sales price of the Shares for amounts of Shares sold pursuant to this Agreement. The Company may also sell Shares to the Agent, acting as principal, at a price agreed upon with the Agent at the relevant Applicable Time and pursuant to a separate Terms Agreement. The remaining proceeds, after further deduction for any transaction fees imposed by any governmental, regulatory or self-regulatory organization in respect of such sales, shall constitute the net proceeds to the Company for such Shares (the "Net Proceeds"). The Agent shall notify the Company as promptly as practicable if any deduction referenced in the preceding sentence will be required.

(e) If acting as a sales agent hereunder, the Agent shall provide written confirmation to the Company promptly following the close of trading on the Nasdaq Global Market, each day in which Shares are sold under this Agreement setting forth the number of Shares sold on such day, the aggregate gross sales proceeds of the Shares, the Net Proceeds to the Company and the compensation payable by the Company to the Agent with respect to such sales.

(f) Under no circumstances shall the aggregate offering price or number, as the case may be, of Shares sold pursuant to this Agreement and any Terms Agreement exceed the aggregate offering price or number, as the case may be, of shares of Common Stock (i) set forth in the preamble paragraph of this Agreement, (ii) available for issuance under the Prospectus and the then currently effective Registration Statement or (iii) authorized from time to time to be issued and sold under this Agreement or any Terms Agreement by the Company's board of directors, or a duly authorized committee thereof, and notified to the Agent in writing. In addition, under no circumstances shall any Shares with respect to which the Agent acts as sales agent be sold in an amount exceeding the number of shares of authorized and unissued shares of Common Stock immediately prior to such sale.

(g) Settlement for sales of Shares pursuant to this Section 2 will occur on the third business day that is also a Trading Day following the trade date on which such sales are made, unless another date shall be agreed to by the Company and the Agent (each such day, a "Settlement Date"). On each Settlement Date, the Shares sold through the Agent for settlement on such date shall be delivered by the Company to the Agent against payment of the Net Proceeds from the sale of such Shares. Settlement for all Shares shall be effected by book-entry delivery of Shares to the Agent's account at The Depository Trust Company against payments by the Agent of the Net Proceeds from the sale of such Shares in same day funds delivered to an account designated by the Company. If the Company shall default on its obligation to deliver Shares on any Settlement Date, the Company shall, in addition to any indemnification obligation pursuant to Section 7, pay the Agent any commission to which it would otherwise be entitled absent such default.

(h) Notwithstanding any other provision of this Agreement, the Company and the Agent agree that no sales of Shares shall take place, and the Company shall not request the sale of any Shares that would be sold, and the Agent shall not be obligated to sell, during any period in which the Company is, or would reasonably be deemed to be, in possession of material non-public information.

(i) Any obligation of the Agent to use its commercially reasonable efforts to sell the Shares on behalf of the Company as sales agent shall be subject to the continuing accuracy of the representations and warranties of the Company herein, to the performance by the Company of its obligations hereunder and to the continuing satisfaction of the additional conditions specified in Section 6 of this Agreement.



Section 3. Covenants. The Company agrees with the Agent:

(a) During any period when the delivery of a prospectus is required in connection with the offering or sale of Shares (whether physically or through compliance with Rule 153 or 172, or in lieu thereof, a notice referred to in Rule 173(a) under the 1933 Act), (i) to make no further amendment or any supplement to the Registration Statement or the Prospectus (other than an amendment or supplement relating to an offering of the Company's securities which is unrelated to the offering of the Shares hereunder) prior to any Settlement Date which shall be disapproved by the Agent promptly after reasonable notice thereof and to advise the Agent, promptly after it receives notice thereof, of the time when any amendment to the Registration Statement has been filed or becomes effective or any amendment or supplement to the Prospectus (other than an amendment or supplement relating to an offering of the Company's securities which is unrelated to the offering of the Shares hereunder) has been filed and to furnish the Agent with copies thereof, (ii) to file promptly all other material required to be filed by the Company with the Commission pursuant to Rule 433(d) under the 1933 Act, (iii) to file promptly all reports and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Section 13(a), 13(c), 14 or 15(d) of the 1934 Act, (iv) to advise the Agent, promptly after it receives notice thereof, of the issuance by the Commission of any stop order or of any order preventing or suspending the use of the Prospectus or other prospectus in respect of the Shares, of the suspension of the qualification of the Shares for offering or sale in any jurisdiction, of the initiation or threatening of any proceeding for any such purpose, or of any request by the Commission for the amending or supplementing of the Registration Statement or the Prospectus or for additional information, and (v) in the event of the issuance of any such stop order or of any such order preventing or suspending the use of the Prospectus in respect of the Shares or suspending any such qualification, to promptly use its commercially reasonable efforts to obtain the withdrawal of such order; and in the event of any such issuance of a notice of objection, promptly to take such reasonable steps as may be necessary to permit offers and sales of the Shares by the Agent, which may include, without limitation, amending the Registration Statement or filing a new registration statement, at the Company's expense (references herein to the Registration Statement shall include any such amendment or new registration statement).

(b) Promptly from time to time to take such action as the Agent may reasonably request to qualify the Shares for offering and sale under the securities laws of such jurisdictions as the Agent may request and to comply with such laws so as to permit the continuance of sales and dealings therein in such jurisdictions for as long as may be necessary to complete the sale of the Shares, provided that in connection therewith the Company shall not be required to qualify as a foreign corporation or to file a general consent to service of process in any jurisdiction; and to promptly advise the Agent of the receipt by the Company of any notification with respect to the suspension of the qualification of the Shares for offer or sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose.

(c) During any period when the delivery of a prospectus is required (whether physically or through compliance with Rules 153 or 172, or in lieu thereof, a notice referred to in Rule 173(a) under the 1933 Act) in connection with the offering or sale of Shares, the Company will make available to the Agent, as soon as practicable after the execution of this Agreement, and thereafter from time to time furnish to the Agent, copies of the most recent Prospectus in such quantities and at such locations as the Agent may reasonably request for the purposes contemplated by the 1933 Act. During any period when the delivery of a prospectus is required (whether physically or through compliance with Rules 153 or 172, or in lieu thereof, a notice referred to in Rule 173(a) under the 1933 Act) in connection with the offering or sale of Shares, and if at such time any event shall have occurred as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made when such Prospectus is delivered, not misleading, or, if for any other reason it shall be necessary during such same period to amend or supplement the Prospectus or to file under the 1934 Act any document incorporated by reference in the Prospectus in order to comply with the 1933 Act or the 1934 Act, to notify the Agent and to file such document and to prepare and furnish without charge to the Agent as many written and electronic copies as the Agent may from time to time reasonably request of an amended Prospectus or a supplement to the Prospectus which will correct such statement or omission or effect such compliance.

(d) To make generally available to its securityholders as soon as practicable, but in any event not later than sixteen months after the effective date of the Registration Statement (as defined in Rule 158(c) under the 1933 Act), an earnings statement of the Company and its subsidiaries (which need not be audited) complying with Section 11(a) of the 1933 Act and the rules and regulations of the Commission thereunder (including, at the option of the Company, Rule 158).

(e) To pay the required Commission filing fees relating to the Shares within the time required by Rule 456(b)(1) under the 1933 Act and otherwise in accordance with Rules 456(b) and 457(r) under the 1933 Act.

(f) To use the Net Proceeds received by it from the sale of the Shares pursuant to this Agreement and any Terms Agreement in the manner specified in the General Disclosure Package.

(g) In connection with the offering and sale of the Shares, the Company will file with the Nasdaq Global Market all documents and notices, and make all certifications, required by the Nasdaq Global Market of companies that have securities that are listed on the Nasdaq Global Market and will maintain such listings.

(h) To not take, directly or indirectly, and to cause its affiliates to refrain from taking, any action designed to cause or result in, or that has constituted or might reasonably be expected to constitute, under the 1934 Act or otherwise, the stabilization or manipulation of the price of any securities of the Company to facilitate the sale or resale of the Shares.

(i) In each Annual Report on Form 10-K or Quarterly Report on Form 10-Q filed by the Company in respect of any quarter in which sales of Shares were made by or through the Agent under this Agreement or any Terms Agreement (each date on which any such document is filed, and any date on which an amendment to any such document is filed, a “Company Periodic Report Date”), the Company shall set forth with regard to such quarter the number of Shares sold through the Agent under this Agreement or any Terms Agreement and the Net Proceeds received by the Company with respect to sales of Shares pursuant to this Agreement or any Terms Agreement.

(j) On or prior to the date of this Agreement, on or prior to the date on which the Company first instructs the Agent to sell Shares pursuant to Section 2(b) hereof or the date of the first Terms Agreement, as applicable (the “First Sales Instruction Date”) and, after the First Sales Instruction Date, at each time the Shares are delivered to the Agent as principal on a Settlement Date and promptly after each (i) date the Registration Statement or the Prospectus shall be amended or supplemented (other than (1) by an amendment or supplement providing solely for the determination of the terms of the Shares, (2) in connection with the filing of a prospectus supplement that contains solely the information set forth in Section 3(i), (3) in connection with the filing of any current reports on Form 8-K (other than any current reports on Form 8-K which contain financial statements, supporting schedules or other financial data of the type required to be filed by the Company pursuant to Regulation S-X of the 1933 Act, including any current report on Form 8-K under Item 2.02 of such form that is considered “filed” under the 1934 Act) or (4) by a prospectus supplement relating to the offering of other securities (including, without limitation, other shares of Common Stock)) (each such date, a “Registration Statement Amendment Date”) and (ii) Company Periodic Report Date, the Company will furnish or cause to be furnished forthwith to the Agent a certificate dated the date of delivery to the Agent, in a form reasonably satisfactory to the Agent to the effect that the statements contained in the certificate referred to in Section 6(d) of this Agreement which were last furnished to the Agent are true and correct at the time of such amendment, supplement or filing, as the case may be, as though made at and as of such time (except that such statements shall be deemed to relate to the Registration Statement, the Disclosure Package and the Prospectus as amended and supplemented to such time) or, in lieu of such certificate, a certificate of the same tenor as the certificate referred to in said Section 6(d), but modified as necessary to relate to the Registration Statement and the Prospectus as amended and supplemented, or to the document incorporated by reference into the Prospectus, to the time of delivery of such certificate. As used in this paragraph, to the extent there shall be an Applicable Time on or following the date referred to in clause (i) or (ii) above, promptly shall be deemed to be any time on or prior to the next succeeding Applicable Time.

(k) On or prior to the date of this Agreement, on or prior to the First Sales Instruction Date and, after the First Sales Instruction Date, at each time the Shares are delivered to the Agent as principal on a Settlement Date and promptly after each (i) Registration Statement Amendment Date and (ii) Company Periodic Report Date, the Company will furnish or cause to be furnished to the Agent the written opinion of Cooley LLP (“Cooley”) or other counsel to the Company reasonably satisfactory to the Agent, in the form attached hereto as Exhibit 3(k)-1, and the written opinion of Sughrue Mion PLLC (“Sughrue”) or other counsel to the Company reasonably satisfactory to the Agent, in the form attached hereto as Exhibit 3(k)-3, in each case dated the date of delivery to the Agent, and in each

case modified as necessary to relate to the Registration Statement, the General Disclosure Package and the Prospectus as amended and supplemented, or to the document(s) incorporated by reference into the Prospectus, to the time of delivery of such opinion and/or letter. In addition, on or prior to the First Sales Instruction Date and, after the First Sales Instruction Date, at each time the Shares are delivered to the Agent as principal on a Settlement Date and promptly after each (i) Registration Statement Amendment Date and (ii) Company Periodic Report Date, the Company will furnish or cause to be furnished to the Agent the letter of Cooley, or other counsel to the Company reasonably satisfactory to the Agent, in the form attached hereto as Exhibit 3(k)-2 and the letter of Sughrue, or other counsel reasonably satisfactory to the Agent, in the form attached hereto as Exhibit 3(k)-3, in each case dated the date of delivery to the Agent, and in each case modified as necessary to relate to the Registration Statement, the General Disclosure Package and the Prospectus as amended and supplemented, or to the document(s) incorporated by reference into the Prospectus, to the time of delivery of such letter or, in lieu of such letter, counsel last furnishing such letter to the Agent shall furnish the Agent with a letter substantially to the effect that the Agent may rely on such last letter to the same extent as though each were dated the date of such letter authorizing reliance (except that statements in such last letter shall be deemed to relate to the Registration Statement and the Prospectus as amended and supplemented to the time of delivery of such letter authorizing reliance). As used in this paragraph, to the extent there shall be an Applicable Time on or following the date referred to in clause (i) or (ii) above, promptly shall be deemed to be any time on or prior to the next succeeding Applicable Time.

(l) On or before the First Sales Instruction Date and, after the First Sales Instruction Date, at each time the Shares are delivered to the Agent as principal on a Settlement Date and promptly after each (i) Registration Statement Amendment Date and (ii) Company Periodic Report Date, the Company will cause Ernst & Young LLP, or other independent registered public accounting firm reasonably satisfactory to the Agent, to furnish to the Agent a letter, dated the date of delivery to the Agent, as the case may be, in form and substance reasonably satisfactory to the Agent and its counsel, containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements of the Company and its subsidiaries included or incorporated by reference in the Registration Statement, the General Disclosure Package and the Prospectus, but modified as necessary to relate to the Registration Statement, the Disclosure Package and the Prospectus, as amended and supplemented, or to the document(s) incorporated by reference into the Prospectus, to the date of such letter. As used in this paragraph, to the extent there shall be an Applicable Time on or following the date referred to in clause (i) or (ii) above, promptly shall be deemed to be any time on or prior to the next succeeding Applicable Time.

(m) The Company consents to Stifel Nicolaus trading in the Company's Common Stock for Stifel Nicolaus' own account and for the account of its clients at the same time as sales of Shares occur pursuant to this Agreement or any Terms Agreement, provided that at all times the Agent is in compliance with Regulation M under the 1934 Act with respect to the Common Stock and provided further that in no event shall the Agent trade the Common Stock for its or its affiliates' proprietary accounts.

(n) [Reserved].

(o) The Company will cooperate timely with any reasonable due diligence review conducted by the Agent or its counsel from time to time in connection with the transactions contemplated hereby or in any Terms Agreement, including, without limitation, and upon reasonable notice providing information and making available documents and appropriate corporate officers, during regular business hours and at the Company's principal offices, as the Agent may reasonably request.

(p) During the time instructions to sell shares delivered pursuant to Section 2(b) hereof or any Terms Agreement is in effect, the Company will not, without giving the Agent at least three business days' prior written notice specifying the nature of the proposed sale and the date of such proposed sale (1) offer, pledge, publicly announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant for the sale of, lend or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or securities convertible into or exchangeable or exercisable for or repayable with Common Stock, or file any registration statement under the 1933 Act with respect to any of the foregoing (other than a shelf registration statement under Rule 415 under the 1933 Act, a registration statement on Form S-8 or post-effective amendment to the Registration Statement) or (2) enter into any swap or other agreement or any transaction that transfers in whole or in part, directly or indirectly, any of the economic consequence of

ownership of the Common Stock, or any securities convertible into or exchangeable or exercisable for or repayable with Common Stock, whether any such swap or transaction described in clause (1) or (2) above is to be settled by delivery of Common Stock or such other securities, in cash or otherwise. The foregoing sentence shall not apply to (x) any securities issuable upon the exercise or conversion of warrants, options, convertible securities or other rights either in existence prior to the date of this Agreement or issued thereafter in compliance with this Section 3 (p), (y) the Shares to be offered and sold through the Agent pursuant to this Agreement or any Terms Agreement and (z) equity incentive awards approved by the board of directors of the Company or any committee thereof or the issuance of Common Stock upon exercise thereof.

(q) If immediately prior to the third anniversary (the “Renewal Deadline”) of the initial effective date of the Registration Statement, any of the Shares remain unsold, the Company will, prior to the Renewal Deadline file, if it has not already done so and is eligible to do so, an “automatic shelf registration statement” (as defined in Rule 405 under the 1933 Act) relating to the Shares, in a form reasonably satisfactory to the Agent. If the Company is not eligible to file an automatic shelf registration statement, the Company will, prior to the Renewal Deadline, if it has not already done so, file a new shelf registration statement relating to the Shares, in a form reasonably satisfactory to the Agent, and will use commercially reasonable efforts to cause such registration statement to be declared effective within 60 days after the Renewal Deadline. The Company will use commercially reasonable efforts to take all other action necessary or appropriate to permit the issuance and sale of the Shares to continue as contemplated in the expired registration statement relating to the Shares. References herein to the Registration Statement shall include such new automatic shelf registration statement or such new shelf registration statement, as the case may be.

#### Section 4. Free Writing Prospectus.

(a) (i) The Company represents and agrees that without the prior consent of the Agent (which consent may not be unreasonably withheld, delayed or conditioned), it has not made and will not make any offer relating to the Shares that would constitute a “free writing prospectus” as defined in Rule 405 under the 1933 Act; and

(ii) the Agent represents and agrees that, without the prior consent of the Company (which consent may be given or withheld by the Company in its sole discretion), it has not made and will not make any offer relating to the Shares that would constitute a free writing prospectus required to be filed with the Commission.

(b) The Company has complied and will comply with the requirements of Rule 433 under the 1933 Act applicable to any Issuer Free Writing Prospectus (including any free writing prospectus identified in Section 4(a) hereof), including timely filing with the Commission or retention where required and legending.

Section 5. Payment of Expenses. The Company covenants and agrees with the Agent that the Company will pay or cause to be paid the following: (i) the fees, disbursements and expenses of the Company’s counsel and accountants in connection with the registration of the Shares under the 1933 Act and all other expenses in connection with the preparation, printing and filing of the Registration Statement, the Basic Prospectus, Prospectus Supplement, any Issuer Free Writing Prospectus and the Prospectus and amendments and supplements thereto and the mailing and delivering of copies thereof to the Agent; (ii) the cost of printing or producing this Agreement or any Terms Agreement, any Blue Sky and Legal Investment Memoranda, closing documents (including any compilations thereof) and any other documents in connection with the offering, purchase, sale and delivery of the Shares; (iii) all fees and expenses in connection with listing the Shares on the Nasdaq Global Market; (iv) the cost of preparing the Shares; (v) the costs and charges of any transfer agent or registrar or any dividend distribution agent; and (vi) all other costs and expenses incident to the performance of its obligations hereunder which are not otherwise specifically provided for in this Section. The Company further covenants and agrees with the Agent that the Company will pay or cause to be paid the Pro Rata (as defined below) portion of the following (collectively, the “Legal Expenses”): (i) all expenses in connection with the qualification of the Shares for offering and sale under state securities laws as provided in Section 3(b) hereof, including the reasonable fees and disbursements of counsel for the Agent in connection with such qualification and in connection with the Blue Sky and Legal Investment Surveys; (ii) any filing fees incident to, and the reasonable fees and disbursements of counsel for the Agent in connection with, any required review by FINRA of the terms of the sale of the Shares; and (iii) the reasonable fees

and expenses of counsel to the Agent in connection with this Agreement and the offering contemplated hereby; provided that in no event shall the amount of Legal Expenses reimbursable exceed \$60,000 in the aggregate. The “Pro Rata” amount shall be equal to the product obtained by multiplying (x) the amount of such Legal Expenses, by (y) 1 minus the quotient of the aggregate offering price of Shares previously sold, divided by the Maximum Offering Size. The Pro Rata portion of the Legal Expenses shall be paid by the Company reasonably promptly following the one (1) year anniversary of the date of this Agreement, or in the event of any termination of this Agreement prior to such time, reasonably promptly following such termination. In addition, in connection with any termination of this Agreement following the one (1) year anniversary of this Agreement, to the extent the Pro Rata portion of Legal Expenses that would be reimbursable by the Company as of the date of such termination is less than the previously reimbursed amount, the Agent shall reasonably promptly reimburse the Company for any such difference. It is understood, however, that, except as provided in this Section, and Section 7 hereof, the Agent will pay all of its own costs and expenses, including the fees of its counsel, transfer taxes on resale of any of the Shares by it, and any advertising expenses connected with any offers it may make.

Section 6. Conditions of Agent’s Obligation. The obligations of the Agent hereunder shall be subject, in its discretion, to the condition that all representations and warranties and other statements of the Company herein or in certificates of any officer of the Company delivered pursuant to the provisions hereof are true and correct as of the time of the execution of this Agreement, the date of any executed Terms Agreement and as of each Registration Statement Amendment Date, Company Periodic Report Date, Applicable Time and Settlement Date, to the condition that the Company shall have performed all of its obligations hereunder theretofore to be performed, and the following additional conditions:

(a) The Prospectus Supplement shall have been filed with the Commission pursuant to Rule 424(b) under the 1933 Act on or prior to the date hereof and in accordance with Section 3(a) hereof, any other material required to be filed by the Company pursuant to Rule 433(d) under the 1933 Act shall have been filed with the Commission within the applicable time periods prescribed for such filings by Rule 433; no stop order suspending the effectiveness of the Registration Statement or any part thereof shall have been issued and no proceeding for that purpose shall have been initiated or threatened by the Commission and no notice of objection of the Commission to the use of the form of the Registration Statement or any post-effective amendment thereto pursuant to Rule 401(g)(2) under the 1933 Act shall have been received; no stop order suspending or preventing the use of the Prospectus or any Issuer Free Writing Prospectus shall have been initiated or threatened by the Commission; and all requests for additional information on the part of the Commission shall have been complied with to the reasonable satisfaction of the Agent.

(b) The Company shall have complied with its obligations in Section 3(k) hereof.

(c) The Company shall have complied with its obligations in Section 3(l) hereof.

(d) (i) On each date on which the Company delivers instructions to sell shares pursuant to Section 2(b) hereof, on the date of each Terms Agreement and on such other dates as reasonably requested by Agent, the Company will furnish or cause to be furnished promptly to the Agent a certificate of an officer in a form reasonably satisfactory to the Agent stating (A) whether the Common Stock is an “actively traded security” exempted from the requirements of Rule 101 of Regulation M under the 1934 Act by subsection (c)(1) of such rule and (B) the minimum price for the sale of such Shares pursuant to this Agreement and the maximum number of Shares that may be issued and sold pursuant to this Agreement or, alternatively, maximum gross proceeds from such sales, as authorized from time to time by the Company’s board of directors or a duly authorized committee thereof or, in connection with any amendment, revision or modification of such minimum price or maximum Share number or amount, a new certificate with respect thereto and (ii) on each date that the Company is obligated to deliver a certificate to the Agent pursuant to Section 3(j), the Agent shall have received a certificate of executive officers of the Company, one of whom shall be the Chief Financial Officer, Chief Accounting Officer, Treasurer, or Executive Vice President in the area of capital markets and investments, dated as of the date thereof, to the effect that (A) there has been no Material Adverse Change since the date as of which information is given in the General Disclosure Package and the Prospectus as then amended or supplemented, (B) the representations and warranties in Section 1 hereof are true and correct as of such date and (C) the Company has complied with all of the agreements entered into in connection with the transaction contemplated herein and satisfied all conditions on its part to be performed or satisfied on or before the date of the certificate.

(e) Since the date of the latest audited financial statements then included or incorporated by reference in the General Disclosure Package and the Prospectus, no Material Adverse Change shall have occurred.

(f) The Company shall have complied with the provisions of Section 3(c) hereof with respect to the timely furnishing of prospectuses.

(g) On such dates as reasonably requested by the Agent, the Company shall have conducted due diligence sessions, in form and substance satisfactory to the Agent.

(h) All filings with the Commission required by Rule 424 under the 1933 Act to have been filed by each Applicable Time or related Settlement Date shall have been made within the applicable time period prescribed for such filing by Rule 424 (without reliance on Rule 424(b)(8)).

(i) The Shares shall have received approval for listing on the Nasdaq Global Market prior to the first Settlement Date.

(j) Prior to any Settlement Date, the Company shall have furnished to the Agent such further information, documents or certificates as the Agent may reasonably request.

#### Section 7. Indemnification.

(a) The Company will indemnify and hold harmless the Agent against any losses, claims, damages or liabilities, joint or several, to which the Agent may become subject, under the 1933 Act or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, the Basic Prospectus, the Prospectus Supplement or the Prospectus or any amendment or supplement thereto, any Issuer Free Writing Prospectus or any "issuer information" filed or required to be filed pursuant to Rule 433(d) under the 1933 Act, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, or arise out of or are based on the Company's failure to deliver Shares on any Settlement Date as required pursuant to Section 2(f), and will reimburse the Agent for any legal or other expenses reasonably incurred by the Agent in connection with investigating or defending any such action or claim as such expenses are incurred; provided, however, that the Company shall not be liable in any such case to the extent that any such loss, claim, damage or liability arises out of or is based upon an untrue statement or alleged untrue statement or omission or alleged omission made in the Registration Statement, the Basic Prospectus, the Prospectus Supplement or the Prospectus, or any amendment or supplement thereto, or any Issuer Free Writing Prospectus, in reliance upon and in strict conformity with written information furnished to the Company by the Agent expressly for use therein.

(b) The Agent will indemnify and hold harmless the Company against any losses, claims, damages or liabilities to which the Company may become subject, under the 1933 Act or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, the Basic Prospectus, the Prospectus Supplement or the Prospectus, or any amendment or supplement thereto, or any Issuer Free Writing Prospectus, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in the Registration Statement, the Basic Prospectus, the Prospectus Supplement or the Prospectus, or any such amendment or supplement thereto, or any Issuer Free Writing Prospectus, in reliance upon and in strict conformity with written information furnished to the Company by the Agent expressly for use therein; and will reimburse the Company for any legal or other expenses reasonably incurred by the Company in connection with investigating or defending any such action or claim as such expenses are incurred.

(c) Promptly after receipt by an indemnified party under subsection (a) or (b) above of notice of the commencement of any action, such indemnified party shall, if a claim in respect thereof is to be made against the indemnifying party under such subsection, notify the indemnifying party in writing of the commencement thereof;

but the omission so to notify the indemnifying party shall not relieve the indemnifying party from any liability which it may have to any indemnified party otherwise than under such subsection except and then only to the extent such indemnifying party is materially prejudiced thereby. In case any such action shall be brought against any indemnified party and it shall notify the indemnifying party of the commencement thereof, the indemnifying party shall be entitled to participate therein and, to the extent that it shall wish, jointly with any other indemnifying party similarly notified, to assume the defense thereof, with counsel satisfactory to such indemnified party (who shall not, except with the consent of the indemnified party, be counsel to the indemnifying party), and, after notice from the indemnifying party to such indemnified party of its election so to assume the defense thereof, the indemnifying party shall not be liable to such indemnified party under this Section 7 for any legal expenses of other counsel or any other expenses, in each case subsequently incurred by such indemnified party, in connection with the defense thereof other than reasonable costs of investigation. No indemnifying party shall, without the written consent of the indemnified party, effect the settlement or compromise of, or consent to the entry of any judgment with respect to, any pending or threatened action or claim in respect of which indemnification or contribution may be sought hereunder (whether or not the indemnified party is an actual or potential party to such action or claim) unless such settlement, compromise or judgment (i) includes an unconditional release of the indemnified party from all liability arising out of such action or claim and (ii) does not include a statement as to or an admission of fault, culpability or a failure to act, by or on behalf of any indemnified party.

(d) If the indemnification provided for in this Section 7 is unavailable to hold harmless an indemnified party under subsection (a) or (b) above in respect of any losses, claims, damages or liabilities (or actions in respect thereof) referred to therein, then each indemnifying party shall contribute to the amount paid or payable by such indemnified party as a result of such losses, claims, damages or liabilities (or actions in respect thereof) in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and the Agent on the other from the offering of the Shares to which such loss, claim, damage or liability (or action in respect thereof) relates. If, however, the allocation provided by the immediately preceding sentence is not permitted by applicable law, then each indemnifying party shall contribute to such amount paid or payable by such indemnified party in such proportion as is appropriate to reflect not only such relative benefits but also the relative fault of the Company on the one hand and the Agent on the other in connection with the statements or omissions which resulted in such losses, claims, damages or liabilities (or actions in respect thereof), as well as any other relevant equitable considerations. The relative benefits received by the Company on the one hand and the Agent on the other shall be deemed to be in the same proportion as the total net proceeds from the offering (before deducting expenses) received by the Company bear to the total commissions received by the Agent. The relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company on the one hand or the Agent on the other and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and the Agent agree that it would not be just and equitable if contribution pursuant to this subsection (d) were determined by pro rata allocation or by any other method of allocation which does not take account of the equitable considerations referred to above in this subsection (d). The amount paid or payable by an indemnified party as a result of the losses, claims, damages or liabilities (or actions in respect thereof) referred to above in this subsection (d) shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this subsection (d), the Agent shall not be required to contribute any amount in excess of the amount by which the total compensation received by the Agent with respect to sales of the Shares sold by it to the public exceeds the amount of any damages which the Agent has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the 1933 Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation.

(e) The obligations of the Company under this Section 7 shall be in addition to any liability which the Company may otherwise have and shall extend, upon the same terms and conditions, to the directors, officers, employees, attorneys and agents of the Agent and to each person, if any, who controls the Agent within the meaning of the 1933 Act and each broker dealer affiliate of the Agent; and the obligations of the Agent under this Section 7 shall be in addition to any liability which the Agent may otherwise have and shall extend, upon the same terms and conditions, to each director, officer, employee, attorney and agent of the Company and to each person, if any, who controls the Company within the meaning of the 1933 Act.

Section 8. Representations, Warranties and Agreements to Survive Delivery. The respective indemnities, agreements, representations, warranties and other statements of the Company and the Agent, as set forth in this Agreement or made by or on behalf of them, respectively, pursuant to this Agreement, shall remain in full force and effect, regardless of any investigation (or any statement as to the results thereof) made by or on behalf of the Agent or any controlling person of the Agent, or the Company, or any officer or director or controlling person of the Company, and shall survive delivery of and payment for the Shares.

Section 9. No Advisory or Fiduciary Relationship. The Company acknowledges and agrees that (i) the Agent is acting solely in the capacity of an arm's length contractual counterparty to the Company with respect to the offering of Shares contemplated hereby (including in connection with determining the terms of such offering) and (ii) the Agent has not assumed an advisory or fiduciary responsibility in favor of the Company with respect to the offering contemplated hereby or the process leading thereto (irrespective of whether the Agent has advised or is currently advising the Company on other matters) or any other obligation to the Company except the obligations expressly set forth in this Agreement and (iii) the Company has consulted its own legal and financial advisors to the extent it deemed appropriate. The Company agrees that it will not claim that the Agent has rendered advisory services of any nature or respect, or owes a fiduciary or similar duty to the Company, in connection with such transaction or the process leading thereto.

Section 10. Termination.

(a) The Company shall have the right, by giving written notice as hereinafter specified, to terminate this Agreement in its sole discretion at any time. Any such termination shall be without liability of any party to any other party, except that (i) with respect to any pending sale through the Agent for the Company, the obligations of the Company, including in respect of compensation of the Agent, shall remain in full force and effect notwithstanding such termination; and (ii) the provisions of Section 1, Section 5, Section 7 and Section 8 of this Agreement shall remain in full force and effect notwithstanding such termination.

(b) The Agent shall have the right, by giving written notice as hereinafter specified, to terminate this Agreement in its sole discretion at any time. Any such termination shall be without liability of any party to any other party, except that (i) with respect to any pending sale through the Agent for the Company, the obligations of the Agent shall remain in full force and effect notwithstanding such termination; and (ii) the provisions of Section 1, Section 5, Section 7 and Section 8 of this Agreement shall remain in full force and effect notwithstanding such termination.

(c) Unless earlier terminated pursuant to this Section 10, this Agreement shall automatically terminate upon the issuance and sale of all of the Shares through the Agent on the terms and subject to the conditions set forth herein; provided that any such termination pursuant to this clause (c) shall in all cases be deemed to provide that Section 1, Section 5, Section 7 and Section 8 of this Agreement shall remain in full force and effect.

(d) This Agreement shall remain in full force and effect until and unless terminated pursuant to Section 10(a), (b) or (c) above or otherwise by mutual agreement of the parties; provided that any such termination by mutual agreement or pursuant to this clause (d) shall in all cases be deemed to provide that Section 1, Section 5, Section 7 and Section 8 of this Agreement shall remain in full force and effect.

(e) Any termination of this Agreement shall be effective on the date specified in such notice of termination; provided that such termination shall not be effective until the close of business on the date of receipt of such notice by the Agent or the Company, as the case may be. If such termination shall occur prior to the Settlement Date for any sale of Shares, such sale shall settle in accordance with the provisions of Section 2(g) hereof.

(f) In the case of any purchase by the Agent pursuant to a Terms Agreement, the Agent may terminate this Agreement, at any time at or prior to the Settlement Date (i) if there has been, since the time of execution of this Agreement or since the respective dates as of which information is given in the General Disclosure Package or the Prospectus, any Material Adverse Change, or (ii) if there has occurred any Material Adverse Change in the financial markets in the United States or the international financial markets, any outbreak of hostilities or escalation thereof or other calamity or crisis or any change or development involving a prospective change in national or international political, financial or economic conditions, in each case the effect of which is such as to make it, in the judgment of



the Agent, impracticable or inadvisable to market the Shares or to enforce contracts for the sale of Shares, or (iii) if trading in any securities of the Company has been suspended or materially limited by the Commission or the Nasdaq Global Market, or if trading generally on the American Stock Exchange or the NYSE or Nasdaq Global Market has been suspended or materially limited, or minimum or maximum prices for trading have been fixed, or maximum ranges for prices have been required, by any of said exchanges or by such system or by order of the Commission, FINRA or any other governmental authority, or (iv) a material disruption has occurred in commercial banking or securities settlement or clearance services in the United States, or (v) if a banking moratorium has been declared by either Federal or New York authorities.

Section 11. Notices. All statements, requests, notices and agreements hereunder shall be in writing, and if to Stifel Nicolaus shall be delivered or sent by mail, telex or facsimile transmission to:

Stifel, Nicolaus & Company, Incorporated  
One South Street, 15<sup>th</sup> Floor  
Baltimore, Maryland 21202  
Fax No. (443) 224-1273  
Attention: Syndicate Department

and if to the Company to:

Vical Incorporated  
10390 Pacific Center Court  
San Diego, CA 92121  
Facsimile: (858) 646-1100  
Attention: President and Chief Executive Officer

Any such statements, requests, notices or agreements shall take effect upon receipt thereof.

Section 12. Parties. This Agreement shall be binding upon, and inure solely to the benefit of, the Agent and the Company and, to the extent provided in Sections 7 and 8 hereof, the officers, directors, employees, attorneys and agents of the Company and the Agent and each person who controls the Company or the Agent, and their respective heirs, executors, administrators, successors and assigns, and no other person shall acquire or have any right under or by virtue of this Agreement. No purchaser of Shares through the Agent shall be deemed a successor or assign by reason merely of such purchase.

Section 13. Time of the Essence. Time shall be of the essence of this Agreement. As used herein, the term "business day" shall mean any day when the Commission's office in Washington, D.C. is open for business.

Section 14. Waiver of Jury Trial. The Company and the Agent hereby irrevocably waive, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

Section 15. Governing Law. THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK WITHOUT REFERENCE TO ITS PRINCIPLES OF CONFLICTS OF LAW.

Section 16. Counterparts. This Agreement and any Terms Agreement may be executed by any one or more of the parties hereto and thereto in any number of counterparts, each of which shall be deemed to be an original, but all such respective counterparts shall together constitute one and the same instrument. This Agreement and any Terms Agreement may be delivered by any party by facsimile or other electronic transmission.

Section 17. Severability. The invalidity or unenforceability of any Section, paragraph or provision of this Agreement shall not affect the validity or enforceability of any other Section, paragraph or provision hereof. If any Section, paragraph or provision of this Agreement is for any reason determined to be invalid or unenforceable, there shall be deemed to be made such minor changes (and only such minor changes) as are necessary to make it valid and enforceable.

---

If the foregoing is in accordance with your understanding of our agreement, please sign and return to the Company a counterpart hereof, whereupon this instrument, along with all counterparts, will become a binding agreement between the Agent and the Company in accordance with its terms.

Very truly yours,

VICAL INCORPORATED

By: /s/ Jill Broadfoot  
Name: Jill Broadfoot  
Title: Chief Financial Officer

Accepted as of the date hereof:

STIFEL, NICOLAUS & COMPANY, INCORPORATED

By: /s/ Daniel J. Covatta  
Name: Daniel J. Covatta  
Title: Managing Director

## VICAL INCORPORATED

Common Stock  
(\$0.01 par value per share)

**TERMS AGREEMENT**

## STIFEL, NICOLAUS &amp; COMPANY, INCORPORATED

One South Street, 15<sup>th</sup> Floor  
Baltimore, MD 21202  
Attn: Syndicate Department

Ladies and Gentlemen:

Vical Incorporated, a Delaware corporation (the “Company”), proposes, subject to the terms and conditions stated herein and in the At-the-Market Equity Offering Sales Agreement, dated November 7, 2012 (the “Sales Agreement”), between the Company and Stifel, Nicolaus & Company, Incorporated (the “Agent”), to issue and sell to the Agent the securities specified and on the terms set forth in Schedule I hereto (the “Purchased Securities”).

Each of the provisions of the Sales Agreement not specifically related to the solicitation by the Agent, as agent of the Company, of offers to purchase securities is incorporated herein by reference in its entirety, and shall be deemed to be part of this Terms Agreement to the same extent as if such provisions had been set forth in full herein. Each of the representations and warranties set forth therein shall be deemed to have been made at and as of the date of this Terms Agreement and the Applicable Time, except that each representation and warranty in Section 1 of the Sales Agreement which makes reference to the Prospectus (as therein defined) shall be deemed to be a representation and warranty as of the date of the Sales Agreement in relation to the Prospectus, and also a representation and warranty as of the date of this Terms Agreement and the Settlement Date in relation to the Prospectus as amended and supplemented to relate to the Purchased Securities.

Subject to the terms and conditions set forth herein and in the Sales Agreement which are incorporated herein by reference, the Company agrees to issue and sell to the Agent and the latter agrees to purchase from the Company the number of shares of the Purchased Securities at the time and place and at the purchase price set forth in Schedule I hereto.

If the foregoing is in accordance with your understanding of our agreement, please sign and return to the Company a counterpart hereof, whereupon this instrument, along with all counterparts, will become a binding agreement between the Agent and the Company in accordance with its terms.

---

Very truly yours,

VICAL INCORPORATED

By: \_\_\_\_\_  
Name:  
Title:

Accepted as of the date hereof:

STIFEL, NICOLAUS & COMPANY, INCORPORATED

By: \_\_\_\_\_  
Name:  
Title:

---

**SCHEDULE I**

A-3

**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:
  - 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 7, 2012

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 7, 2012

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, 2012, 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 7, 2012

/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, 2012, 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 7, 2012

/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.