

ANTIGENICS INC /DE/  
Form 10-Q  
November 09, 2009  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 10-Q**

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the Quarterly Period Ended September 30, 2009

**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: 000-29089

**Antigenics Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of

**06-1562417**  
(I.R.S. Employer

incorporation or organization)

Identification No.)

**3 Forbes Road, Lexington, MA 02421**

(Address of principal executive offices, including zip code)

**(781) 674-4400**

(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐  
(Do not check if a smaller

Smaller reporting company ☐

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 ☒

Number of shares outstanding of the registrant's Common Stock as of November 4, 2009: 89,739,446 shares.

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**Antigenics Inc.**

**Quarterly Period Ended September 30, 2009**

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**Table of Contents****PART I FINANCIAL INFORMATION****Item 1. Financial Statements****ANTIGENICS INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS****(Unaudited)**

	<b>September 30, 2009</b>	<b>December 31, 2008 As adjusted</b>
<b>ASSETS</b>		
Cash and cash equivalents	\$ 29,010,953	\$ 24,469,008
Short-term investments	4,997,535	9,993,617
Accounts receivable	325,126	
Inventories	23,669	226,376
Prepaid expenses	915,154	610,462
Other current assets	694,341	187,013
Total current assets	35,966,778	35,486,476
Plant and equipment, net	9,432,498	11,535,467
Goodwill	2,572,203	2,572,203
Core and developed technology, net	1,596,338	2,426,785
Debt issuance costs, net (Note I)	327,281	717,833
Other long-term assets	1,455,279	4,083,442
Total assets	\$ 51,350,377	\$ 56,822,206
<b>LIABILITIES AND STOCKHOLDERS DEFICIT</b>		
Current portion, long-term debt	\$ 146,061	\$ 146,061
Current portion, deferred revenue	1,435,537	1,481,999
Accounts payable	660,928	540,529
Accrued liabilities	3,269,282	4,618,806
Other current liabilities	675,274	209,585
Total current liabilities	6,187,082	6,996,980
Long-term debt (Note I)	47,966,163	64,125,926
Deferred revenue	2,765,396	3,436,845
Derivative liability (Note I)	10,915,353	
Other long-term liabilities	2,426,363	2,592,882
Commitments and contingencies (Note E)		
Stockholders' deficit:		
Preferred stock, par value \$0.01 per share; 25,000,000 shares authorized:		
Series A convertible preferred stock; 31,620 shares designated, issued, and outstanding at September 30, 2009 and December 31, 2008; liquidation value of \$31,817,625 at September 30, 2009	316	316
Series B2 convertible preferred stock; 3,105 and 5,250 shares designated, issued, and outstanding at September 30, 2009 and December 31, 2008, respectively	31	53
	899,755	664,977

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Common stock, par value \$0.01 per share; 250,000,000 shares authorized; 89,975,583 and 66,497,702 shares issued at September 30, 2009 and December 31, 2008, respectively

Additional paid-in capital	544,886,359	511,447,653
Treasury stock, at cost; 260,944 and 143,031 shares of common stock at September 30, 2009 and December 31, 2008, respectively	(324,792)	(269,849)
Accumulated deficit	(564,371,649)	(532,173,577)
Total stockholders' deficit	(18,909,980)	(20,330,427)
Total liabilities and stockholders' deficit	\$ 51,350,377	\$ 56,822,206

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents****ANTIGENICS INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(Unaudited)**

	<b>Quarter Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008 As adjusted</b>	<b>2009</b>	<b>2008 As adjusted</b>
Revenue	\$ 896,462	\$ 684,566	\$ 2,787,653	\$ 2,129,503
Operating expenses:				
Research and development	3,747,180	5,395,804	13,680,290	16,965,309
General and administrative	3,516,127	5,132,204	11,589,216	16,141,706
Operating loss	(6,366,845)	(9,843,442)	(22,481,853)	(30,977,512)
Other income (expense):				
Non-operating (expense) income	(3,039,372)		(5,679,769)	2,310
Interest expense	(1,224,578)	(1,614,930)	(4,137,186)	(4,771,260)
Interest income	18,182	213,776	121,984	870,655
Net loss	(10,612,613)	(11,244,596)	(32,176,824)	(34,875,807)
Dividends on series A convertible preferred stock	(197,625)	(197,625)	(592,875)	(592,875)
Net loss attributable to common stockholders	\$ (10,810,238)	\$ (11,442,221)	\$ (32,769,699)	\$ (35,468,682)
Per common share data, basic and diluted:				
Net loss attributable to common stockholders	\$ (0.13)	\$ (0.17)	\$ (0.43)	\$ (0.57)
Weighted average number of common shares outstanding, basic and diluted	85,801,855	66,208,764	75,334,382	62,194,760

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents****ANTIGENICS INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(Unaudited)**

	<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008 As adjusted</b>
Cash flows from operating activities:		
Net loss	\$ (32,176,824)	\$ (34,875,807)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,106,654	3,547,186
Disposal of fixed assets	48,774	14,227
Change in fair value of derivative liability	8,202,490	
Share-based compensation	3,375,158	4,813,468
Net gain on extinguishment of debt	(2,653,387)	
Loss on monetization of receivable	317,512	
Non-cash interest expense	2,486,883	2,046,207
Changes in operating assets and liabilities:		
Accounts receivable	(325,126)	318,707
Inventories	202,707	284,496
Prepaid expenses	(304,692)	(32,905)
Accounts payable	101,061	17,836
Deferred revenue	(717,911)	(1,052,817)
Accrued liabilities and other current liabilities	(1,507,423)	1,295,818
Other operating assets and liabilities	(716,089)	(76,449)
Net cash used in operating activities	(20,560,213)	(23,700,033)
Cash flows from investing activities:		
Proceeds from maturities of available-for-sale securities	25,000,000	14,162,968
Proceeds from sale of property and equipment	39,525	
Collection of receivable from sale of patent applications	2,337,475	
Purchases of available-for-sale securities	(19,988,500)	(19,917,910)
Purchases of plant and equipment	(116,420)	(133,437)
Net cash provided by (used in) investing activities	7,272,080	(5,888,379)
Cash flows from financing activities:		
Net proceeds from sale of equity	18,582,501	46,545,177
Proceeds from exercise of stock options	133,462	46,562
Payment of long-term debt	(255,000)	
Proceeds from employee stock purchases	16,933	286,931
Treasury stock received to satisfy minimum tax withholding requirements	(54,943)	(257,681)
Payment of series A convertible preferred stock dividends	(592,875)	(592,875)
Net cash provided by financing activities	17,830,078	46,028,114
Net increase in cash and cash equivalents	4,541,945	16,439,702
Cash and cash equivalents, beginning of period	24,469,008	14,479,322
Cash and cash equivalents, end of period	\$ 29,010,953	\$ 30,919,024

Non-cash investing and financing activities:

Issuance of senior secured convertible notes as payment in-kind for interest	\$ 1,185,456	\$ 1,096,021
Issuance of common stock, \$0.01 par value, as payment of long-term debt including accrued and unpaid interest	14,134,188	

See accompanying notes to unaudited condensed consolidated financial statements.



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### **ANTIGENICS INC. AND SUBSIDIARIES**

#### **NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2009**

#### **Note A Business and Basis of Presentation**

Antigenics Inc. (including its subsidiaries, also referred to as Antigenics, the Company, we, us, and our ) is a biotechnology company developing and commercializing technologies to treat cancers and infectious diseases, primarily based on immunological approaches. Our most advanced product, Oncophage® (vitespen), is a patient-specific therapeutic cancer vaccine registered for use in Russia. As resources allow, we explore potential opportunities to seek product approval in other jurisdictions. Oncophage has been tested in Phase 3 clinical trials for the treatment of renal cell carcinoma, the most common type of kidney cancer, and for metastatic melanoma, and it has also been tested in Phase 1 and Phase 2 clinical trials in a range of indications. It is currently in Phase 2 clinical trials in glioma, a type of brain cancer. Our product candidate portfolio also includes (1) QS-21 Stimulon® adjuvant, or QS-21, which is used in numerous vaccines in clinical trials as advanced as Phase 3 for a variety of diseases, including hepatitis, human immunodeficiency virus, influenza, cancer, Alzheimer's disease, malaria, and tuberculosis, (2) AG-707, a therapeutic vaccine program tested in a Phase 1 clinical trial for the treatment of genital herpes, and (3) Aroplatin, a liposomal chemotherapeutic tested in a Phase 1 clinical trial for the treatment of solid malignancies and B-cell lymphomas. Further internal clinical development of AG-707 and Aroplatin is currently on hold due to cost-containment efforts. Our related business activities include product research and development, intellectual property prosecution, manufacturing therapeutic vaccines, regulatory and clinical affairs, corporate finance and development activities, market development, and support of our collaborations.

Our product candidates require clinical trials and approvals from regulatory agencies, as well as acceptance in the marketplace. Part of our strategy is to develop and commercialize some of our product candidates by continuing our existing arrangements with academic and corporate collaborators and licensees and by entering into new collaborations.

We have incurred significant losses since our inception. As of September 30, 2009, we had an accumulated deficit of \$564.4 million. Since our inception, we have financed our operations primarily through the sale of equity and convertible notes, interest income earned on cash, cash equivalents, and short-term investment balances, and debt provided through secured lines of credit. We believe that, based on our current plans and activities, our working capital resources at September 30, 2009, anticipated revenues, and the estimated proceeds from our license, supply, and collaborative agreements, will be sufficient to satisfy our liquidity requirements into 2011. We closely monitor our cash needs. We continue to monitor the likelihood of success of our key initiatives and are prepared to discontinue funding of such activities if they do not prove to be commercially feasible. In addition, we will continue to adjust other spending as needed in order to preserve liquidity. We expect to attempt to raise additional funds in advance of depleting our current funds. We may attempt to raise additional funds by: (1) licensing technologies or products to one or more collaborative partners, (2) renegotiating license and/or supply agreements with current licensees or collaborative partners, (3) completing an outright sale of assets, (4) securing additional debt financing, and/or (5) selling additional equity securities. Satisfying long-term liquidity needs may require the successful commercialization of (1) our product, Oncophage, and/or one or more partnering arrangements for Oncophage, (2) vaccines containing QS-21 under development by our licensees, and/or (3) potentially other product candidates, and will require additional capital.

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ( GAAP ) for interim financial information and with the instructions to Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete annual consolidated financial statements. In the opinion of management, the condensed consolidated financial statements include all normal and recurring adjustments considered necessary for a fair presentation of our financial position and operating results. All significant intercompany transactions and accounts have been eliminated in consolidation. Certain amounts previously reported have been adjusted in order to conform to the current period's presentation, including changes resulting from the January 1, 2009 adoption of Financial Accounting Standards Board ( FASB ) Staff Position APB 14-1, Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement), contained within Accounting Standards Codification ( ASC ) 470-20, Debt with Conversion and Other Options. Operating results for the nine months ended September 30, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009. For further information, refer to our consolidated financial statements and footnotes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2008 filed with the Securities and Exchange Commission (the SEC ).

The preparation of consolidated financial statements in conformity with U.S. GAAP 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. Management bases its estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances. Actual results could differ materially from those estimates.

**Note B   Net Loss Per Share**

Basic loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding (including common shares issuable under our Directors' Deferred Compensation Plan). Diluted loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding (including common shares issuable under our Directors' Deferred Compensation Plan) plus the dilutive effect of outstanding convertible instruments such as warrants, stock options, nonvested shares, convertible preferred stock, and convertible notes. Because we have reported a net loss attributable to common stockholders for all periods, diluted loss per common share is the same as basic loss per common share, as the effect of utilizing the fully diluted share count would have reduced

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the net loss per common share. Therefore, shares underlying the warrants outstanding or issuable to acquire 41,966,718 shares, the outstanding stock options to acquire 6,430,105 shares, the 216,938 outstanding nonvested shares, the 31,620 outstanding shares of series A convertible preferred stock, the 3,105 outstanding shares of series B2 convertible preferred stock, and the impact of conversion of our 5.25% convertible senior notes due February 2025 (the 2005 Notes ) and our 8% senior secured convertible notes due August 2011 (the 2006 Notes ), are not included in the calculation of diluted net loss per common share.

**Note C Inventories**

Inventories are stated at cost using the first-in, first-out method. The components of inventories are as follows (in thousands).

	September 30, 2009	December 31, 2008
Work in process	\$	\$ 194
Finished goods	24	32
	\$ 24	\$ 226

**Note D Share-Based Compensation**

We use the Black-Scholes option pricing model to value options for employees and non-employees as well as options granted to members of our Board of Directors. All stock option grants have a 10-year term and generally vest ratably over a four-year period. The non-cash charge to operations for non-employee options with vesting or other performance criteria is affected each reporting period, until the non-employee options vest, by changes in the fair value of our common stock.

A summary of option activity for the nine months ended September 30, 2009 is presented below:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2008	7,873,464	\$ 5.00		
Granted	1,509,584	1.63		
Exercised	(74,276)	1.80		
Forfeited	(408,665)	2.16		
Expired	(2,470,002)	9.00		
Outstanding at September 30, 2009	6,430,105	\$ 2.89	7.5	\$ 1,665,000
Vested or expected to vest at September 30, 2009	6,249,257	\$ 2.92	7.5	\$ 1,595,000
Exercisable at September 30, 2009	3,188,750	\$ 3.93	6.3	\$ 641,490

The weighted average grant-date fair values of options granted during the nine months ended September 30, 2009 and 2008 were \$1.21 and \$1.06, respectively.

During the first nine months of 2009, all options were granted with exercise prices equal to the fair market value of the underlying shares of common stock on the grant date. On July 16, 2009, we accepted for cancellation options to purchase 1,594,876 shares of common stock in accordance with the terms of our Tender Offer as included in our Schedule TO filed with the SEC on June 17, 2009. As a result, on July 16, 2009, we granted options to purchase 1,196,161 shares of common stock pursuant to and subject to the terms and conditions of the Tender Offer

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dated June 17, 2009. The exercise price of each option granted is \$1.58 per share, which was the closing price of our common stock as reported by the NASDAQ Capital Market on July 16, 2009. The incremental stock-based compensation expense related to the Tender Offer will be recognized over the vesting period of the new options.

As of September 30, 2009, \$1.9 million of total unrecognized compensation cost related to stock options granted to employees and directors is expected to be recognized over a weighted average period of 1.9 years.

As of September 30, 2009, unrecognized expense for options granted to outside advisors for which performance (vesting) has not yet been completed but the exercise price of the option is known is \$227,000. Such amount is subject to change each reporting period based upon changes in the fair value of our common stock, expected volatility, and the risk-free interest rate, until the outside advisor completes his or her performance under the option agreement.

Certain employees and consultants have been granted nonvested stock. The fair value of nonvested stock is calculated based on the closing sale price of the Company's common stock on the date of issuance.

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A summary of nonvested stock activity for the nine months ended September 30, 2009 is presented below:

	Nonvested Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2008	966,450	\$ 1.54
Granted	1,661,295	0.75
Vested	(2,355,782)	1.03
Forfeited	(55,025)	1.30
Outstanding at September 30, 2009	216,938	\$ 1.13

As of September 30, 2009, there was \$212,000 of unrecognized share-based compensation expense related to these nonvested shares. This cost is expected to be recognized over a weighted average period of 1.9 years. The total intrinsic value of shares vested during the nine months ended September 30, 2009 was \$4.9 million.

Cash received from purchases under the 1999 Employee Stock Purchase Plan (the 1999 ESPP) and exercises of options under the 1999 Equity Incentive Plan for the nine months ended September 30, 2009 was approximately \$17,000 and \$133,000, respectively. We issue new shares upon option exercises, purchases under the 1999 ESPP, vesting of nonvested stock, and under the Directors' Deferred Compensation Plan. During the nine months ended September 30, 2009, 41,300 shares were issued under the 1999 ESPP, 74,276 shares were issued upon the exercise of options, and approximately 2,210,000 shares, net of 118,000 shares withheld to cover personal income tax withholding, were issued as a result of the vesting of nonvested stock. The shares withheld were recorded as treasury stock using the cost method, at a weighted average price of \$0.47 per share, based on the NASDAQ Global Market closing price on the vesting dates, for a total cost of approximately \$55,000. In addition, during the nine months ended September 30, 2009, approximately 15,000 shares were issued under our Directors' Deferred Compensation Plan.

The impact on our results of operations from the granting of stock options and nonvested shares was as follows (in thousands).

	Quarter Ended September 30, 2009      2008		Nine Months Ended September 30, 2009      2008	
Research and development	\$ 101	\$ 79	\$ 1,072	\$ 1,428
General and administrative	832	821	2,303	3,385
Total share-based compensation expense	\$ 933	\$ 900	\$ 3,375	\$ 4,813

**Note E Commitments and Contingencies**

Antigenics, our Chairman and Chief Executive Officer, Garo H. Armen, Ph.D., and two investment banking firms that served as underwriters in our initial public offering have been named as defendants in a federal civil class action lawsuit pending in the United States District Court for the Southern District of New York. Substantially similar actions were filed concerning the initial public offerings for more than 300 different issuers, and the cases were coordinated as *In re Initial Public Offering Securities Litigation*, 21 MC 92 for pre-trial purposes. The suit alleges that the brokerage arms of the investment banking firms charged secret excessive commissions to certain of their customers in return for allocations of our stock in the offering. The suit also alleges that shares of our stock were allocated to certain of the investment banking firms customers based upon agreements by such customers to purchase additional shares of our stock in the secondary market. Dr. Armen has been dismissed without prejudice from the lawsuit pursuant to a stipulation. In June 2004, a stipulation of settlement and release of claims against the issuer defendants, including us, was submitted to the Court for approval. The Court preliminarily approved the settlement in August 2005. In December 2006, the appellate court overturned the certification of classes in six test cases that were selected by the underwriter defendants and plaintiffs in the coordinated proceedings. Class certification had been one of the conditions of the settlement. Accordingly, on June 25, 2007, the Court entered an order terminating the proposed settlement based on a stipulation among the parties to the settlement. Plaintiffs have filed amended master allegations and amended complaints and moved for class certification in the six test cases, which the defendants in those cases

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have opposed. On March 26, 2008, the Court largely denied the defendants' motion to dismiss the amended complaints. The parties have reached a global settlement of the litigation. Under the settlement, the insurers will pay the full amount of settlement share allocated to the defendants, and the defendants will bear no financial liability. The company defendants, as well as the officer and director defendants who were previously dismissed from the action pursuant to tolling agreements, will receive complete dismissals from the case. On October 5, 2009, the Court entered an order granting final approval of the settlement. Certain objectors are seeking to appeal. If for any reason the settlement does not become effective, we believe we have meritorious defenses to the claims and intend to defend the action vigorously. We are unable to predict the likelihood of an unfavorable outcome or estimate our potential liability, if any. No accrual has been recorded at September 30, 2009 for this action.

We may currently be, or may become, a party to other legal proceedings as well. The ultimate outcome of any such proceedings is subject to inherent uncertainty. Furthermore, litigation consumes both cash and management attention.

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### Note F License and Supply Agreements

On July 6, 2006, we and GlaxoSmithKline Biologicals SA ( GSK ) entered into an expanded license agreement (the GSK License Agreement ) and an expanded Manufacturing Technology Transfer and Supply Agreement (the 2006 GSK Supply Agreement ) for the use of QS-21, an investigational adjuvant used in numerous vaccines under development. Under the terms of the agreements, we agreed to supply QS-21 to GSK through 2014. In addition, we agreed to transfer manufacturing technologies under the 2006 GSK Supply Agreement. In conjunction with the GSK License Agreement and the 2006 GSK Supply Agreement, we received a \$3.0 million up-front non-refundable payment in July 2006. In February 2007, we received and recorded \$2.0 million as revenue as a result of the achievement of a milestone related to the transfer of manufacturing technologies to GSK.

On July 20, 2007, we executed a letter (the GSK Letter ) with GSK amending the 2006 GSK Supply Agreement to accelerate GSK's commercial grade QS-21 manufacturing rights previously granted in July 2006. On January 16, 2009, we entered into an Amended and Restated Manufacturing Technology Transfer and Supply Agreement (the Amended GSK Supply Agreement ) reflecting the provisions of the letter.

Accordingly, from the effective date of the GSK Letter, GSK has the right to manufacture all of its requirements of commercial grade QS-21. In addition, the parties have amended their purchase and supply obligations with respect to pre-commercial grade QS-21. In accordance with the terms of the Amended GSK Supply Agreement, upon our election, GSK is obligated to supply us (or our affiliates, licensees, or customers) certain quantities of commercial grade QS-21 for a stated period of time.

As consideration for our entering into the GSK Letter, we received a \$2.0 million up-front non-refundable payment from GSK in August 2007, in lieu of a milestone payment that would have otherwise been payable under the 2006 GSK Supply Agreement. In addition, GSK is obligated to make payments to us totaling \$5.25 million through December 2012, of which \$1.75 million has been received, for manufacturing profits that were anticipated to have otherwise been earned under the 2006 GSK Supply Agreement. Except as expressly provided in the Amended GSK Supply Agreement, all other financial obligations of GSK under the 2006 GSK Supply Agreement, including royalty payments, remain unchanged. The Amended GSK Supply Agreement does not affect the rights and obligations of the parties under the GSK License Agreement.

During each of the nine months ended September 30, 2009 and 2008, we recognized revenue of \$995,000 from the amortization of deferred revenue relating to payments received under our license and supply agreements with GSK. Deferred revenue of \$3.5 million related to our agreements with GSK is included in deferred revenue on our consolidated balance sheet as of September 30, 2009.

Effective September 14, 2009, we entered into an Amended and Restated License Agreement ( Amended License Agreement ) with Elan Pharma International Limited and Elan Pharmaceuticals, Inc. On September 17, 2009, the Amended License Agreement was assigned to JANSSEN Alzheimer Immunotherapy, a subsidiary of Johnson & Johnson. Under the terms of the Amended License Agreement assigned to JANSSEN Alzheimer Immunotherapy, they will have the right to develop, make, have made, use, sell, offer for sale, import, and have sold the Alzheimer's disease vaccine that contains QS-21 ( Licensed Product ). In addition, pursuant to the terms of the Amended License Agreement, JANSSEN Alzheimer Immunotherapy has the right to manufacture all of its requirements of QS-21 for use in the Licensed Product and we have no further supply obligations. As consideration, we received an upfront payment and are entitled to receive payments contingent upon successful milestone achievements. In addition, we are entitled to receive royalties on a country-by-country basis on net sales of Licensed Product for a period of at least 10 years after first commercial sale in that country. Deferred revenue of \$396,000 related to this Amended License Agreement is included in deferred revenue on our consolidated balance sheet as of September 30, 2009.

### Note G Restructuring Costs

On February 2, 2009, we initiated a plan of restructuring that resulted in a reduction of our workforce by approximately 20%, or 19 positions. We engaged in this workforce reduction in order to reduce operating expenses in light of current market conditions and to focus our resources on near-term commercial opportunities. This restructuring action resulted in total charges of approximately \$177,000 in severance and outplacement expenses in the quarter ended March 31, 2009, with \$42,000 included in research and development expenses and \$135,000 included in general and administrative expenses in our consolidated statement of operations. The charge to operations was reduced by \$10,000 during the quarter ended June 30, 2009 based on actual activities. A summary of these costs is as follows (in thousands):

	Liability at December 31, 2008	Charge to Operations	Amounts Paid	Liability at September 30, 2009
Severance	\$	\$ 150	\$ (150)	\$

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Outplacement		17	(17)
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Total	\$	\$	167	\$	(167)	\$
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## **Note H Recent Accounting Pronouncements**

In June 2009, the FASB issued the ASC as the single source of authoritative U.S. GAAP recognized by the FASB to be applied by nongovernmental entities in preparation of financial statements in conformity with U.S. GAAP. While the adoption of the ASC as of September 30, 2009 changes how we reference accounting standards, the adoption did not have an impact on our financial position, results of operations, or cash flows.

In December 2007, the FASB issued authoritative guidance that expands the types of transactions or other events that will



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qualify as business combinations and requires that all business combinations will result in all assets and liabilities of the acquired business being recorded at their fair values, with limited exceptions. The guidance also requires, among other provisions, that certain contingent assets and liabilities will be recognized at their fair values on the acquisition date. An acquirer will also recognize contingent consideration at its fair value on the acquisition date and, for certain arrangements, changes in fair value will be recognized in earnings until the contingency is settled. Under this guidance, acquisition-related transaction and restructuring costs will be expensed rather than treated as part of the cost of the acquisition and included in the amount recorded for assets acquired. This guidance is required to be applied prospectively to business combinations for which the acquisition is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. The adoption of this authoritative guidance did not have an impact on our financial position or results of operations.

In December 2007, the FASB issued authoritative guidance, which is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008, that governs the accounting for and reporting of noncontrolling interests in partially owned consolidated subsidiaries and the loss of control in subsidiaries. The adoption of this authoritative guidance did not have an impact on our financial position or results of operations.

In March 2008, the FASB issued authoritative guidance, which is effective for fiscal years, and interim periods within those fiscal years, beginning on or after November 15, 2008, that is intended to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity's financial position, financial performance and cash flows. The adoption of this authoritative guidance did not have an impact on our financial position or results of operations but required additional disclosure (see Note J).

In May 2008, the FASB revised authoritative guidance, which is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2008, that specifies that issuers of convertible debt instruments that may be settled in cash upon conversion should separately account for the liability and equity components in a manner that will reflect the entity's nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. We adopted this revised guidance as of January 1, 2009 and the effect on our consolidated financial statements is discussed in Note I.

In June 2008, the FASB ratified revised guidance, which is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, that defines when adjustment features within contracts are considered to be equity-indexed. We adopted this guidance, which is applicable to our 2006 Notes due to the provisions contained therein that protect the holders from declines in our stock price, as of January 1, 2009. This guidance is applied prospectively, with a cumulative effect adjustment recorded to accumulated deficit as of January 1, 2009, as if the revised guidance had been applied to the 2006 Notes since their issuance. See Note I for additional information as to the effect of the adoption of this revised guidance.

In April 2009, the FASB issued revised guidance requiring an acquirer to recognize at the acquisition date the fair value of an asset acquired or liability assumed in a business combination that arises from a contingency, if the acquisition-date fair value can be determined during the measurement period. This revised guidance is effective for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. This revised guidance impacts our accounting for future business combinations, if any.

In April 2009, the FASB also issued revised guidance with respect to estimating fair value when the volume and level of activity for the asset or liability have significantly decreased. This revised guidance also focuses on identifying circumstances that indicate a transaction is not orderly. The revised guidance emphasizes that even if there has been a significant decrease in the volume and level of activity for the asset or liability and regardless of the valuation technique(s) used, the objective of a fair value measurement remains the same. This guidance is effective for interim and annual reporting periods ending after June 15, 2009, and is to be applied prospectively with early adoption permitted for periods ending after March 15, 2009. The adoption of this guidance did not have an impact on our consolidated financial statements.

In April 2009, the FASB issued revised guidance amending the other-than-temporary impairment guidance for debt securities to make the guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. This revision does not amend existing recognition and measurement guidance related to other-than-temporary impairments of equity securities. This guidance is effective for interim and annual reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. The adoption of this revised guidance did not have an impact on our consolidated financial statements.

In April 2009, the FASB issued revised guidance to require disclosures about the fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. This revised guidance also requires those disclosures in summarized financial information at interim reporting periods. This authoritative guidance is effective for interim reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. The adoption of this authoritative guidance did not have an impact

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on our financial position or results of operations but required additional disclosure (see Notes I and J).

In May 2009, the FASB issued authoritative guidance establishing general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued. This guidance also requires entities to disclose the date through which subsequent events were evaluated as well as the rationale for why that date was selected. This guidance is effective for interim and annual periods ending after June 15, 2009. The adoption of this guidance did not have an impact on our financial position or results of operations. We evaluated all events or transactions that occurred after September 30, 2009 up through November 9, 2009, the date our financials were issued. During this period, we did not have any material recognized or nonrecognized subsequent events.

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In June 2009, the FASB issued Statement of Financial Accounting Standards ( SFAS ) No. 166, *Accounting for Transfers of Financial Assets* ( SFAS No. 166 ). SFAS No. 166 amends SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities* ( SFAS No. 140 ), by removing the concept of a qualifying special-purpose entity from SFAS No. 140 and removing the exception from applying FASB Interpretation No. 46, *Consolidation of Variable Interest Entities (revised December 2003)* ( FIN No. 46R ) to variable interest entities that are qualifying special-purpose entities. It also modifies the financial-components approach used in SFAS No. 140. SFAS No. 166 is effective for transfers of financial assets occurring on or after January 1, 2010. The adoption of SFAS No. 166 may impact the accounting for future transactions, if any.

In June 2009, the FASB issued revised guidance which amends the guidelines for determining the existence of a variable interest entity and the related primary beneficiary. This revised guidance also requires ongoing reassessments of whether an enterprise is the primary beneficiary of a variable interest entity. The provisions of this guidance are effective for annual periods beginning after November 15, 2009, with early adoption prohibited. We do not expect the adoption of the provisions of this revised guidance to have a significant impact on our consolidated financial statements.

In October 2009, the FASB revised authoritative guidance on multiple-deliverable revenue arrangements providing a greater ability to separate and allocate arrangement consideration in a multiple-element revenue arrangement by requiring the use of estimated selling price to allocate arrangement consideration, thereby eliminating the use of the residual method of allocation. The revised guidance also requires expanded qualitative and quantitative disclosures surrounding multiple-deliverable revenue arrangements. This guidance is effective for fiscal years beginning after June 15, 2010 and may be applied retrospectively or prospectively for new or materially modified arrangements. Early adoption is permitted. We will evaluate the impact, if any, of this guidance on revenue transactions that we may enter into in the future.

### **Note I Convertible Debt**

As of January 1, 2009, we adopted revised authoritative guidance that addressed certain matters applicable to convertible debt instruments and retrospectively applied this change in accounting to all prior periods presented for which we had applicable outstanding convertible debt, as required by this new guidance. All prior periods presented herein have been adjusted to apply the new method retrospectively. Under this new method of accounting, the debt and equity components of our 2005 Notes and our 2006 Notes are bifurcated and accounted for separately based on the fair value and related interest rate of a non-convertible debt security with the same terms. The fair value of a non-convertible debt instrument at the original issuance dates of our 2005 Notes and our 2006 Notes was determined to be \$42.6 million and \$23.6 million, respectively. The equity (conversion options) components of our convertible debt securities have been included in additional paid-in capital on our consolidated balance sheet and, accordingly, the initial carrying value of the debt securities was reduced by \$8.8 million. Our previously reported net loss for the quarter and nine months ended September 30, 2008 was increased by \$313,000 and \$919,000 respectively, primarily due to recognizing the accretion of the reduced carrying values of our convertible debt securities to their face amount as additional non-cash interest expense. The adoption of this accounting standard has resulted in a reduction in the carrying value of our convertible debt by approximately \$3.7 million as of December 31, 2008. In addition, our deferred debt issuance costs were reduced by \$294,000 as we were required to allocate an amount related to the conversion option to equity.

As a result of the adoption of revised authoritative guidance as of January 1, 2009, the conversion feature embedded in our 2006 Notes is now treated as a derivative and recorded at its fair value, with period to period changes in the fair value recorded as a gain or loss in our consolidated statement of operations. Accordingly, upon adoption we recorded a reduction to additional paid-in capital of \$1.4 million, an increase to debt discount of \$1.3 million, a derivative liability of \$2.7 million, and a charge to opening accumulated deficit of \$21,000. For the quarter and nine months ended September 30, 2009, we have recorded a charge to other expense of \$3.4 million and \$8.2 million, respectively, due to changes in the fair value of the derivative. Interest expense includes \$117,000 and \$502,000 of non-cash interest expense for the quarter and nine months ended September 30, 2009, respectively.

Interest on the 2006 Notes is payable semi-annually on December 30 and September 30 in cash or, at our option, in additional notes or a combination thereof. During the nine months ended September 30, 2009 and 2008, we issued additional 2006 Notes in the amounts of \$1.2 million and \$1.1 million, respectively, as payment for interest due.

During May 2009, we repurchased \$1.0 million of our 2005 Notes for \$255,000 plus accrued interest of \$13,000. In addition, during June 2009, we issued 5,173,000 shares of our common stock as consideration for \$15.9 million of our 2005 Notes including accrued interest of \$282,000. In September 2009, we issued 424,300 shares of our common stock as consideration for \$1.3 million of our 2005 Notes including accrued interest. In connection with the repurchases, we recorded a net gain of \$2.7 million in non-operating income, which is comprised of inducement expense of \$9.8 million and a gain on extinguishment of debt of \$12.5 million for the nine months ended September 30, 2009.

### **Note J Fair Value Measurements**

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We measure fair value based on a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

Level 1 Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access;

Level 2 Valuations based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly; and

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Level 3 Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level input that is significant to the overall fair value measurement.

We measure our short-term investments and derivative liability at fair value. Our short-term investments are comprised of U.S. Treasury securities that are valued using quoted market prices with no valuation adjustments applied. Accordingly, these securities are categorized in Level 1. Our derivative liability is classified within Level 3 because it is valued using a modified Black-Scholes model.

Certain inputs into this model were valued using a combination of income and market approaches which are unobservable in the market and are significant. The estimated fair values of all of our financial instruments, excluding long-term debt, approximate their carrying amounts in the consolidated balance sheets. The fair value of our long-term debt was derived by evaluating the nature and terms of each note and considering the prevailing economic and market conditions at the balance sheet date.

Assets and liabilities measured at fair value are summarized below (in thousands):

Description	September 30, 2009	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>			
Short-term investments	\$ 4,998	\$ 4,998	\$
<b>Liabilities:</b>			
Derivative liability	\$ 10,915	\$	\$ 10,915

The following table presents our liabilities measured at fair value using significant unobservable inputs (Level 3), as of September 30, 2009 (amounts in thousands):

Balance, December 31, 2008	\$
Cumulative effect of change in accounting principle adoption of EITF	
Issue No. 07-5 (contained in ASC 815-40)	2,713
Increase in fair value for the nine months ended September 30, 2009	8,202
Balance, September 30, 2009	\$ 10,915

The increase in fair value of the derivative liability is included in non-operating expense in our condensed consolidated statement of operations for the nine months ended September 30, 2009.

As of September 30, 2009, \$20.0 million in principal of the 2005 Notes are outstanding with an estimated fair value of \$14.9 million based on the most recent market transactions. As of September 30, 2009, \$30.8 million in principal of the 2006 Notes are outstanding. The fair value of the debt portion of the 2006 Notes exclusive of the conversion option is \$30.5 million based on a present value methodology.

**Note K Equity**

In April 2009, we issued 5,929,212 shares of our common stock upon conversion of 2,145 shares of our series B2 convertible preferred stock via cashless conversions. These shares were issued pursuant to an effective registration statement. Upon completion of this conversion, 3,105 shares of our series B2 convertible preferred stock are still outstanding although no further shares can be converted into shares of common stock. In addition, in June 2009, we issued 5,173,000 shares of our common stock as consideration for \$15.9 million of our 2005 Notes including accrued interest of \$282,000. In September 2009, we issued 424,300 shares of our common stock as consideration for \$1.3 million of our 2005 Notes including accrued interest (see Note I).

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On July 30, 2009, we entered into a private placement agreement under which we issued and sold (i) 5,000,000 shares of our common stock, (ii) six-month warrants to purchase up to 2,500,000 additional shares of common stock at an exercise price of \$2 per share, and (iii) four-year warrants to purchase up to 2,173,900 additional shares of common stock at an exercise price of \$2.30 per share, for \$2.00 for each share sold generating gross proceeds of \$10.0 million.

In August 3, 2009, we entered into a private placement agreement under which we issued and sold (i) 4,385,965 shares of our common stock, (ii) six-month warrants to purchase up to 2,192,982 additional shares of common stock at an exercise price of \$2.31 per share, and (iii) four-year warrants to purchase up to 1,973,685 additional shares of common stock at an exercise price of \$2.50 per share, for \$2.28 for each share sold generating gross proceeds of \$10.0 million. The warrants are not exercisable for the first six months following the closing, which occurred on August 4, 2009.

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

We are currently researching and/or developing technologies and product candidates to treat cancers and infectious diseases. Since our inception in March 1994, our activities have primarily been associated with the development of our heat shock protein technology and our product, Oncophage® (vitespen), a patient-specific therapeutic cancer vaccine registered for use in Russia for the treatment of kidney cancer patients at intermediate risk for disease. As resources allow, we explore potential opportunities to seek product approval in other jurisdictions. Oncophage has been tested in Phase 3 clinical trials for the treatment of renal cell carcinoma, the most common type of kidney cancer, and for the treatment of metastatic melanoma, and it has also been tested in Phase 1 and Phase 2 clinical trials in a range of indications. It is currently in Phase 2 clinical trials in glioma, a type of brain cancer. Our business activities have included product research and development, intellectual property prosecution, manufacturing therapeutic vaccines, regulatory and clinical affairs, corporate finance and development activities, market development, and support of our collaborations.

We have incurred significant losses since our inception. As of September 30, 2009, we had an accumulated deficit of \$564.4 million. Since our inception, we have financed our operations primarily through the sale of equity and convertible notes, interest income earned on cash, cash equivalents, and short-term investment balances, and debt provided through secured lines of credit. We believe that, based on our current plans and activities, our working capital resources at September 30, 2009, anticipated revenues, and the estimated proceeds from our license, supply, and collaborative agreements will be sufficient to satisfy our liquidity requirements into 2011. We expect to attempt to raise additional funds in advance of depleting our current funds. We may attempt to raise additional funds by: (1) licensing technologies or products to one or more collaborative partners, (2) renegotiating license and/or supply agreements with current licensees or collaborative partners, (3) completing an outright sale of assets, (4) securing additional debt financing, and/or (5) selling additional equity securities. Satisfying long-term liquidity needs may require the successful commercialization of (1) our product, Oncophage and/or one or more partnering arrangements for Oncophage, (2) vaccines containing QS-21 under development by our licensees, and/or (3) potentially other product candidates, and will require additional capital.

On February 2, 2009, we initiated a plan of restructuring that resulted in a reduction of our workforce by approximately 20%, or 19 positions. We engaged in this workforce reduction in order to reduce operating expenses in light of current market conditions and to focus our resources on near-term commercial opportunities. This restructuring action resulted in charges of approximately \$167,000 in severance and outplacement expenses in the nine months ended September 30, 2009. All of these expenses have been paid as of September 30, 2009.

In April 2008, the Russian Ministry of Public Health issued a registration certificate for the use of Oncophage for the treatment of kidney cancer patients at intermediate risk for disease recurrence and, in September 2008, the U.S. Food and Drug Administration ( FDA ) granted the necessary permission to allow for the export of Oncophage from the United States for patient administration in Russia. The Russian registration was our first product approval from a regulatory authority, and the first approval of a patient-specific therapeutic cancer vaccine in a major market. Since approval, our focus in Russia has been on pre-commercial launch activities.

In October 2008, we announced the submission of a marketing authorization application ( MAA ) to the European Medicines Agency ( EMEA ) requesting conditional authorization of Oncophage in earlier-stage, localized kidney cancer. Conditional authorization, a relatively new provision, is reserved for products intended to treat serious and life-threatening diseases where a high unmet medical need currently exists. On October 20, 2009, the Committee for Medicinal Products for Human Use ( CHMP ) of the EMEA informed us at an oral hearing to anticipate a negative opinion on this MAA. We are currently evaluating our options to determine the best path forward with Oncophage in this territory.

In addition, we are exploring the steps necessary to make Oncophage available in other markets directly or through one or more partnering arrangements. This exploration process includes formal and informal discussions with international regulatory authorities, key opinion leaders, and consultants with country-specific regulatory experience regarding potential applications for full or conditional marketing approval, and/or named patient programs.

Guidance received from past interaction with the FDA indicated that further clinical studies must be conducted to demonstrate the efficacy and safety of Oncophage. At the appropriate time, we intend to seek a meeting with the FDA to discuss the results of the updated analyses from our Phase 3 renal cell carcinoma trial utilizing data through March 2007 as well as based on continued data collection through the follow-on survival registry protocol to determine whether there is an opportunity to file a biologics license application ( BLA ), on the basis of these results with appropriate commitments to conduct further post-approval trials. Because the primary evidence of efficacy comes from a subgroup analysis of the pre-specified primary and secondary endpoints and was not demonstrated in the intent-to-treat population, this trial is likely not sufficient as sole support for product approval based on existing standards in the United States and potentially in other territories.

### **Forward-Looking Statements**

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This Quarterly Report on Form 10-Q contains forward-looking statements. Generally, these statements can be identified by the use of terms like believe, expect, anticipate, plan, may, will, could, estimate, potential, opportunity, future, project, and similar terms.

Forward-looking statements include, but are not limited to, statements about generating sales from Oncophage in Russia, generating royalty revenue from QS-21 in 2011 or thereafter, our or our partners' or licensees' intentions for executing plans or timelines for performing and completing research, preclinical studies and clinical trials, and releasing data, plans or timelines for



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initiating new clinical trials, expectations regarding research, preclinical studies, clinical trials, and regulatory processes (including additional clinical studies for Oncophage in renal cell carcinoma), expectations regarding test results, future product research and development activities, the expected effectiveness and safety profile of therapeutic drugs, vaccines, and combinations in treating diseases, statements regarding the potential benefit of Oncophage in kidney cancer based on a subgroup analysis, as well as other potential benefits of Oncophage based on preliminary clinical data, applicability of our heat shock protein technology to multiple cancers and infectious diseases, competitive position, regulatory plans and actions, including with respect to regulatory filings and meetings and communications with regulatory authorities (including potential requests for meetings with the FDA regarding Oncophage clinical studies and strategies for responding to the CHMP's decision regarding the conditional authorization of Oncophage in Europe and for making Oncophage available in other territories), the sufficiency of our clinical trials in renal cell carcinoma and melanoma, or subgroup analyses of data from these trials, to support a BLA or foreign marketing application for product approval, possible receipt of future regulatory approvals, the performance of collaborative partners in, and revenue expectations from, our strategic license and partnering collaborations, expected liquidity and cash needs, plans to commence, accelerate, decelerate, postpone, discontinue, or resume clinical programs, the rate of our net cash burn (defined as cash used in operating activities plus capital expenditures, debt repayments, and dividend payments), plans for commercial launch, and sales and marketing activities in Russia, implementation of corporate strategy, increased foreign currency exposure when we commercialize in Russia, and future financial performance.

These forward-looking statements involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested by the forward-looking statements. These risks and uncertainties include, among others, that clinical trials may not demonstrate that our products are safe and more effective than current standards of care; that the subgroup analyses of our Oncophage clinical trials do not predict survival or efficacy of the product in future studies or use of Oncophage; that we may be unable to obtain sufficient funding or the regulatory authorization necessary to conduct additional clinical trials; that we may not be able to enroll sufficient numbers of patients in our clinical trials; that we may be unable to obtain the regulatory review or approval necessary to commercialize our product candidates because regulatory agencies are not satisfied with our trial protocols or the results of our trials; that we may fail to adequately protect our intellectual property or that it is determined that we infringe on the intellectual property of others; our strategic licenses and partnering collaborations may not meet expectations; that we or our business partners may fail to take all steps necessary for the successful commercial launch of Oncophage in Russia; that we may not be able to secure adequate reimbursement mechanisms and/or private-pay for Oncophage in Russia; that we may not continue to pursue a marketing authorization application for Oncophage with the EMEA, and that even if we do continue such pursuit, Oncophage may not achieve conditional approval in Europe, because we may not successfully address issues associated with post-hoc analysis, subgroup analysis, lack of immunological data in renal cell carcinoma, product characterization, or other issues that may be of concern to the EMEA; that named patient programs may not be launched in the near-term, if ever, and if launched may not generate significant revenue, if any; that manufacturing problems may cause product development and launch delays and unanticipated costs; our ability to raise additional capital; our ability to attract and retain key employees; changes in financial markets, regulatory requirements, and geopolitical developments; the solvency of counterparties under material agreements, including subleases; and general real estate risks.

We have included more detailed descriptions of these risks and uncertainties and other risks and uncertainties applicable to our business in Part II-Item 1A. Risk Factors of this Quarterly Report on Form 10-Q. We encourage you to read those descriptions carefully. We caution investors not to place significant reliance on forward-looking statements contained in this document; such statements need to be evaluated in light of all the information contained in this document. Furthermore, the statements speak only as of the date of this document, and we undertake no obligation to update or revise these statements.

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## **Results of Operations**

### ***Quarter Ended September 30, 2009 Compared to the Quarter Ended September 30, 2008***

**Revenue:** We generated revenue of \$896,000 and \$685,000 during the quarters ended September 30, 2009 and 2008, respectively. The increase is primarily due to an increase in revenue earned on shipments of QS-21 to our QS-21 licensees in the quarter ended September 30, 2009 as compared to the quarter ended September 30, 2008, primarily due to timing, and an increase in royalties earned. In the quarters ended September 30, 2009 and 2008, we recorded revenue of \$387,000 and \$361,000, respectively, from the amortization of deferred revenue.

**Research and Development:** Research and development expenses include the costs associated with our internal research and development activities, including compensation and benefits, occupancy costs, clinical manufacturing costs, administrative costs, and services provided by clinical research organizations. Research and development expense decreased 31% to \$3.7 million for the quarter ended September 30, 2009 from \$5.4 million for the quarter ended September 30, 2008. The decrease includes declines related to our general cost-containment efforts and to the status of our products under development partially offset by the increase in shipments of QS-21.

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*General and Administrative:* General and administrative expenses consist primarily of personnel costs, facility expenses, and professional fees. General and administrative expenses decreased 31% to \$3.5 million for the quarter ended September 30, 2009 from \$5.1 million for the quarter ended September 30, 2008. This decrease is largely related to our general cost containment.

*Non-Operating Expense:* Non-operating expense of \$3.0 million for the quarter ended September 30, 2009 consists primarily of the change in the fair value of our derivative liability since June 30, 2009 of \$3.4 million primarily due to an increase in our market value, partially offset by net proceeds received from a legal settlement and the net gain on the extinguishment of a portion of our 5.25% convertible senior notes due February 2025 (the 2005 Notes ).

*Interest Expense:* Interest expense decreased to \$1.2 million for the quarter ended September 30, 2009 from \$1.6 million for the quarter ended September 30, 2008. This decrease is related to the repurchase of a portion of our 2005 Notes during the fourth

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quarter of 2008 and the second quarter of 2009. Interest on our 8% senior secured convertible notes due August 2011 (the 2006 Notes ) is payable semi-annually on December 30 and June 30 in cash or, at our option, in additional notes or a combination thereof. During the quarters ended September 30, 2009 and 2008, interest expense included \$616,000 and \$563,000, respectively, related to the 2006 Notes.

*Interest Income:* Interest income decreased to \$18,000 for the quarter ended September 30, 2009 from \$214,000 for the same period in 2008. This decrease is attributable to a decrease in our average cash, cash equivalents, and short-term investments balance coupled with a decrease in interest rates earned on such items. Our average interest rate earned decreased from 1.9% for the quarter ended September 30, 2008 to 0.3% for the quarter ended September 30, 2009.

### *Nine Months Ended September 30, 2009 Compared to the Nine Months Ended September 30, 2008*

*Revenue:* We generated revenue of \$2.8 million and \$2.1 million during the nine months ended September 30, 2009 and 2008, respectively. The increase is primarily due to an increase for the nine months ended September 30, 2009 over the same period in 2008 in revenue earned on shipments of QS-21 to our QS-21 licensees and an increase in royalties earned. In the nine months ended September 30, 2009 and 2008, we recorded revenue of \$1.1 million each period from the amortization of deferred revenue.

*Research and Development:* Research and development expenses include the costs associated with our internal research and development activities, including compensation and benefits, occupancy costs, clinical manufacturing costs, administrative costs, and services provided by clinical research organizations. Research and development expense decreased 19% to \$13.7 million for the nine months ended September 30, 2009 from \$17.0 million for the nine months ended September 30, 2008. The decrease includes declines related to our general cost-containment efforts and to the status of our products under development.

*General and Administrative:* General and administrative expenses consist primarily of personnel costs, facility expenses, and professional fees. General and administrative expenses decreased 28% to \$11.6 million for the nine months ended September 30, 2009 from \$16.1 million for the nine months ended September 30, 2008. This decrease is largely related to our general cost-containment efforts and a decrease in non-cash share-based compensation expense primarily attributable to a general decline in our stock price year over year.

*Non-Operating Expense:* Non-operating expense of \$5.7 million for the nine months ended September 30, 2009 consists of the change in the fair value of our derivative liability since December 31, 2008 of \$8.2 million primarily due to an increase in our market value, and a loss of \$318,000 from the monetization of the receivable that was received in the 2008 assignment of certain patent applications, partially offset by the net gain of \$2.7 million on the extinguishment of a portion of our 2005 Notes.

*Interest Expense:* Interest expense decreased 13% to \$4.1 million for the nine months ended September 30, 2009 from \$4.8 million for the nine months ended September 30, 2008. This decrease is related to the repurchase of a portion of our 2005 Notes during the fourth quarter of 2008 and second quarter of 2009. Interest on our 2006 Notes is payable semi-annually on December 30 and September 30 in cash or, at our option, in additional notes or a combination thereof. During the nine months ended September 30, 2009 and 2008, interest expense included \$1.8 million and \$1.1 million, respectively, related to the 2006 Notes.

*Interest Income:* Interest income decreased to \$122,000 for the nine months ended September 30, 2009 from \$871,000 for the same period in 2008. This decrease is attributable to a decrease in our average cash, cash equivalents, and short-term investments balance coupled with a decrease in interest rates earned on such items. Our average interest rate earned decreased from 2.8% for the nine months ended September 30, 2008 to 0.5% for the nine months ended September 30, 2009.

## Research and Development Programs

Prior to 2002, we did not track costs on a per project basis, and therefore have estimated the allocation of our total research and development costs to our largest research and development programs for that time period. During the nine months ended September 30, 2009, our focus was primarily on Oncophage, as indicated in the following table (in thousands).

Research and Development Program	Product	Nine Months Ended September 30,	Year Ended December 31,			Prior to	Total
		2009	2008	2007	2006	2006	

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Heat Shock Proteins for Cancer	Oncophage	\$	12,244	\$ 17,156	\$ 13,970	\$ 19,985	\$ 204,471	\$ 267,826	
Heat Shock Proteins for Infectious Diseases	AG-702/707		250	1,377	2,005	1,939	12,127	17,698	
Liposomal Cancer Treatments*	Aroplatin		104	865	3,005	2,475	9,092	15,541	
Vaccine Adjuvant**	QS-21		1,027	648	2,064	2,492	4,944	11,175	
Other Research and Development Programs			55	617	745	1,752	14,626	17,795	
Total Research and Development Expenses			\$	13,680	\$ 20,663	\$ 21,789	\$ 28,643	\$ 245,260	\$ 330,035

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\* Prior to 2001, costs were incurred by Aronex Pharmaceuticals, Inc., a company we acquired in July 2001.

\*\* Prior to 2000, costs were incurred by Aquila Biopharmaceuticals, Inc., a company we acquired in November 2000.

Research and development program costs include compensation and other direct costs plus an allocation of indirect costs, based on certain assumptions and our review of the status of each program. Our product, Oncophage, and our product candidates are in various stages of development as described below. Significant additional expenditures will be required if we start new trials, encounter delays in our programs, apply for regulatory approvals, continue development of our technologies, expand our operations, and/or bring Oncophage and our product candidates to market. The eventual total cost of each clinical trial is dependent on a number of factors such as trial design, length of the trial, number of clinical sites, and number of patients. The process of obtaining and maintaining regulatory approvals for new therapeutic products is lengthy, expensive, and uncertain. Because the further development of Oncophage is subject to further evaluation and uncertainty, and because AG-707 and Aroplatin are in early-stage clinical development and currently on hold due to cost-containment efforts, we are unable to reliably estimate the cost of completing our research and development programs, the timing of bringing such programs to various markets, and, therefore, when, if ever, material cash inflows are likely to commence. Programs involving QS-21 depend on our collaborative partners or licensees successfully completing clinical trials, successfully manufacturing QS-21 to meet demand, obtaining regulatory approvals and successfully commercializing product candidates containing QS-21.

**Product Development Portfolio**

Below is a table showing the clinical trials completed or ongoing in our product portfolio.

**PRODUCT**

PIPELINE		Phase 1	Phase 2	Phase 3
<b>Oncophage</b>	Renal cell carcinoma (e)(f)			
	Metastatic melanoma			
	Glioma (c)(d)			
	Colorectal cancer			
	Non-Hodgkin's lymphoma			
	Gastric cancer (a)			
	Metastatic renal cell carcinoma (b)			
	Lung cancer			
	Metastatic melanoma (a)			
	Pancreatic cancer			
<b>Aroplatin</b>	Colorectal cancer			
	Solid malignancies/ Non-Hodgkin's lymphoma			
	Solid malignancies			
<b>AG-707</b>	Genital herpes			

(a) Phase 1/2 trials.

(b) Includes two separate Phase 1/2 and Phase 2 trials.

(c) Trial is ongoing.

(d) Investigator-sponsored trials, including one Phase 1/2 and one Phase 2 trial.

(e) Approved for use in Russia for the treatment of kidney cancer patients at intermediate risk for disease recurrence.

(f) A registry to monitor patient survival is ongoing.

*Oncophage*

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We started enrolling patients in our first clinical trial studying Oncophage at Memorial Sloan-Kettering Cancer Center in New York, New York in November 1997. To date, investigators in our clinical trials have administered Oncophage to nearly 800 cancer patients. Because Oncophage is a novel therapeutic cancer vaccine that is patient-specific, meaning it is derived from the patient's own tumor, it is experiencing a long regulatory review process and high development costs, either of which could delay or prevent our commercialization efforts. For additional information regarding regulatory risks and uncertainties, please read the risks identified under Part II-Item 1A. Risk Factors of this Quarterly Report on Form 10-Q.

We believe that the collective results from our clinical trials thus far show that Oncophage has a favorable safety profile. We also believe that available results from clinical trials suggest that treatment with Oncophage can generate immunological and anti-tumor responses.

An investigator-sponsored Phase 1/2 clinical trial in recurrent, high-grade glioma is currently ongoing. This study is being lead by the Brain Tumor Research Center at the University of California, San Francisco ( UCSF ), with grants from the American Brain Tumor Association and the National Cancer Institute Special Programs of Research Excellence. Phase 1 results, presented at the

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Society for Neuro-Oncology Annual Meeting Conference in November 2008, showed that Oncophage vaccination following brain cancer surgery increased overall median survival to approximately 10.5 months, with four patients surviving beyond 12 months and one patient surviving almost 2.5 years. This is compared to a historical median survival of only 6.5 months post surgery. The study also showed that all 12 treated patients demonstrated a significant immune response after vaccination with Oncophage ( $P < 0.001$ ) and that patients with minimal residual disease at time of first vaccination ( $n = 7$ ) were more likely to survive beyond nine months compared with patients with significant residual disease. The study has progressed to Phase 2, which is designed to enroll 50 patients, and has expanded to include New York-Presbyterian Hospital/Columbia University Medical Center. Data from the Phase 2 portion was presented at the Society for Neuro-Oncology meeting in October 2009 which showed a median survival of 10.1 months in the first 20 patients treated with Oncophage, and that to date six patients (30 percent) had survived at or beyond 12 months. This early data shows an improvement in overall survival over the previous long-standing historical median survival of 6.5 months, which is also slightly favorable to the recently reported median survival of 9.2 months with Avastin® (bevacizumab) in patients with recurrent high-grade glioma. UCSF also recently initiated an additional Phase 2 clinical trial in newly diagnosed glioma testing Oncophage in combination with Temodar® (temozolomide). This trial is designed to enroll approximately 60 patients.

On March 24, 2006, we announced top-line results from part I of our Phase 3 study of Oncophage in renal cell carcinoma patients who are at high risk of recurrence after surgery, and disclosed that the trial did not meet its primary endpoint. We subsequently announced the termination of part II of the trial.

The Eastern Cooperative Oncology Group is currently sponsoring a large adjuvant renal cell carcinoma trial that stratifies patients by certain prognostic risk factors for recurrence, and puts patients into intermediate risk, high risk, and very high risk categories. We are able to apply these definitions to the data generated as part of our Phase 3 trial of Oncophage in renal cell carcinoma, and it is in the intermediate risk, or better-prognosis population, where significant improvement in favor of the Oncophage arm was demonstrated.

We have opened a subsequent protocol that will continue to follow patients in the format of a registry in order to collect overall survival information, as well as investigator reports of disease recurrence. The registry, which is expected to provide additional data on the effectiveness of Oncophage, is currently designed to follow patients until March 2010, an additional three years from closure of the initial trial, providing more than five years of data collection following the enrollment of the last patient in the trial. At the 2009 American Society of Clinical Oncology annual meeting, we announced results of an interim analysis from the ongoing global patient survival registry, which showed that patients with kidney cancer at intermediate risk of disease recurrence demonstrated an approximately 46 percent lower risk of death when treated with Oncophage cancer vaccine after surgery compared with no treatment ( $n = 362$ ;  $P = 0.036$ ; hazard ratio = 0.54).

In addition to the patient registry, we are in the early initiation stage of a small study in non-metastatic renal cell carcinoma to assess immune response in the intermediate-risk patient population. The results of this study continued data collection through the survival registry and ongoing analyses are uncertain, and may not positively affect the acceptability of the overall results of the trial and, even if clinically meaningful, may not meet the requirements of the FDA or other regulatory authorities for submission and approval of a marketing application or similar applications for product approval outside the United States.

In April 2008, the Russian Ministry of Public Health issued a registration certificate for the use of Oncophage for the treatment of kidney cancer patients at intermediate risk for disease recurrence and, in September 2008, the FDA granted the necessary permission to allow for the export of Oncophage from the United States for patient administration in Russia. The Russian registration was our first product approval from a regulatory authority, and the first approval of a patient-specific therapeutic cancer vaccine in a major market. Since approval we have been focusing our efforts in Russia on pre-commercial launch activities.

We have obtained an import/export license from the Russian Ministry of Industry and Trade but prior to commercial launch we, or our distributors, must also complete a number of other post-approval activities. Since Oncophage can only be manufactured from a patient's own tumor, patients will need to be diagnosed, and their tumors will need to be removed and sent to our manufacturing facility for vaccine to be prepared, released, and then returned to the site for patient administration. Complexities unique to the logistics of commercial products may delay shipments and limit our ability to move commercial product in an efficient manner without incident. In addition, if we are unable to establish and execute on successful local distribution arrangements including favorable pricing and payment terms, and/or implement appropriate logistical processes for distribution of Oncophage, our commercialization efforts may be adversely affected.

Even if we successfully meet the logistical and regulatory requirements for Russian launch, the amount of revenue generated, if any, from the sale of Oncophage in Russia will depend on, among other things, identifying sources of reimbursement and obtaining adequate reimbursement, including from national or regional funds, and physician and patient assessments of the benefits and cost-effectiveness of Oncophage. If we are unsuccessful in obtaining substantial reimbursement for Oncophage from national or regional funds, we will have to rely on private-pay for the foreseeable future, which may delay or prevent our launch efforts because the ability and willingness of patients to pay is unclear. Many patients will not be capable of paying for Oncophage by themselves. In addition, cost-containment measures by third parties may prevent us from

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becoming profitable. Because, among other things, we have limited resources and minimal sales and marketing experience, commercial launch of Oncophage has been slow. Furthermore, we may experience significant delays in the receipt of payment for Oncophage, or an inability to collect payments at all.

In October 2008, we announced the submission of a MAA to the EMEA requesting conditional authorization of Oncophage in earlier-stage, localized kidney cancer. On October 20, 2009 the CHMP of the EMEA informed us at an oral hearing to anticipate a negative opinion on this MAA. We are currently evaluating our options to determine the best path forward for Oncophage. We do not know what impact, if any, this opinion will have on our Russian activities. If we continue to pursue a marketing authorization application for Oncophage there is a high level of uncertainty regarding the probability and timing of a favorable outcome.



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Conditional authorization, a relatively new provision, is reserved for products intended to treat serious and life-threatening diseases where a high unmet medical need currently exists. Specifically, conditional authorization allows for the commercialization of a product with post-approval commitments associated with the requirement to provide comprehensive clinical information about the product's efficacy and safety profile. Products receiving conditional authorization are required to undergo annual regulatory evaluation and renewal until all commitments are fulfilled. Currently, there are no EMEA-approved drug therapies for this patient population. If we continue to pursue a marketing authorization application for Oncophage, there is no guarantee that Oncophage will receive conditional authorization in Europe.

In addition, we are exploring the steps necessary to make Oncophage available in other markets outside the United States directly or through one or more partnering arrangements. This exploration process includes formal and informal discussions with international regulatory authorities, key opinion leaders, consultants and potential partners with country-specific regulatory experience regarding potential applications for full or conditional marketing approvals, and/or named patient programs. There is no guarantee that we will succeed in making Oncophage available in these markets.

Guidance received from past interaction with the FDA indicated that further clinical studies must be conducted to demonstrate the efficacy and safety of Oncophage. At the appropriate time, we intend to seek a meeting with the FDA to discuss the results of the updated analyses from our Phase 3 renal cell carcinoma trial utilizing data through March 2007 to determine whether there is an opportunity to file a BLA on the basis of these results with appropriate commitments to conduct further post-approval trials. Because the primary evidence of efficacy comes from a subgroup analysis of the pre-specified primary and secondary endpoints and was not demonstrated in the intent-to-treat population, this trial is likely not sufficient as sole support for product approval based on existing standards. Furthermore, this trial ultimately may not be sufficient to support approval in additional countries.

### *QS-21*

QS-21 is an adjuvant, or a substance added to a vaccine and other immunotherapy, that is designed to enhance the body's immune response to the antigen contained within the treatment. QS-21 is best known for its ability to stimulate antibody, or humoral, immune response, and has also been shown to activate cellular immunity. A natural product, QS-21 is a triterpene glycoside, or saponin, a natural compound purified from the bark of a South American tree called quillaja saponaria. It is sufficiently characterized with a known molecular structure, thus distinguishing it from other adjuvant candidates, which are typically emulsions, polymers, or biologicals.

QS-21 has been tested in approximately 185 clinical trials involving, in the aggregate, over 10,000 subjects in a variety of cancer indications, infectious diseases, and other disorders. These studies have been carried out by academic institutions located in the United States and internationally. A number of these studies have shown QS-21 to be significantly more effective in stimulating antibody responses than aluminum hydroxide or aluminum phosphate, the adjuvants most commonly used in approved vaccines in the United States today.

A number of pharmaceutical and biotechnology companies have licensed QS-21 for use in vaccines to treat a variety of human diseases. Companies with QS-21 programs include GlaxoSmithKline Biologicals SA ( GSK ) and JANSSEN Alzheimer Immunotherapy, a subsidiary of Johnson & Johnson. In return for rights to use QS-21, these companies have generally agreed to pay us license fees, manufacturing payments, milestone payments, and royalties on product sales for a minimum of 10 years after commercial launch, independent of patent life. In addition to our corporate licensing arrangements, we have developed a number of academic collaborations to test new vaccine concepts and products containing QS-21. There are approximately 15 vaccines currently in clinical development that contain QS-21.

On July 20, 2007, we executed a letter of intent with GSK amending a supply agreement that we have with GSK to accelerate GSK's commercial grade QS-21 manufacturing rights previously granted in July 2006. Accordingly, from the effective date of the letter, GSK has the right to manufacture all of its requirements of commercial grade QS-21. In addition, the parties have amended their purchase and supply obligations with respect to pre-commercial grade QS-21. Also, in accordance with the terms of the letter, upon our election, GSK is obligated to supply us (or our affiliates, licensees, or customers) certain quantities of commercial grade QS-21 for a stated period of time. On January 16, 2009, we entered into an Amended and Restated Manufacturing Technology Transfer and Supply Agreement reflecting the provisions of the letter. We understand that QS-21 is a key component included in several of GSK's proprietary adjuvant systems and that a number of GSK's vaccine candidates currently under development are formulated using adjuvant systems containing QS-21. GSK has initiated Phase 3 studies evaluating its investigational MAGE-A3 Antigen-Specific Cancer Immunotherapeutic containing QS-21 in non-small cell lung cancer and melanoma. GSK has also initiated a Phase 3 clinical trial in malaria.

Elan Corporation, plc, through its affiliate Elan Pharmaceuticals International Limited, ( Elan ) had a commercial license for the use of QS-21 in research and commercialization of products. Effective September 14, 2009, we entered into an Amended and Restated License Agreement ( Amended License Agreement ) with Elan. On September 17, 2009, the Amended License Agreement was assigned to JANSSEN Alzheimer Immunotherapy. Under the terms of the Amended License Agreement assigned to JANSSEN Alzheimer Immunotherapy, they will have the right to develop, make, have made, use, sell, offer for sale, import, and have sold, the Alzheimer's disease vaccine that contains QS-21 ( Licensed

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Product ). In addition, pursuant to the terms of the Amended License Agreement, JANSSEN Alzheimer Immunotherapy has the right to manufacture all of its requirements of QS-21 for use in the Licensed Product and we have no further supply obligations. Under the terms of the Amended License Agreement, we are entitled to receive future milestone payments and product royalties in the event of the successful development of the Licensed Product. In 2007, Elan initiated a Phase 2 study of their vaccine.

*AG-707*

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The first potential off-the-shelf application of our heat shock protein technology, AG-707, is an investigational therapeutic vaccine product candidate directed at the virus that causes genital herpes (herpes simplex virus-2, or HSV-2). AG-707 is a multivalent vaccine containing multiple synthetic HSV-2 peptides. Based on the results of completed toxicology studies and other preclinical activities, we submitted to the FDA an investigational new drug application for AG-707 during the second quarter of 2005. In October 2005, we initiated a multicenter Phase 1 clinical trial of AG-707 in genital herpes. Immunological testing in this study has been completed and final study data review is in process. Further internal work on this program is on hold due to cost-containment efforts. However, we would consider licensing and/or co-development opportunities to advance the product.

### *Aroplatin*

Aroplatin is a novel liposomal formulation of a third-generation platinum chemotherapeutic structurally similar to Eloxatin (oxaliplatin; Sanofi Aventis), a treatment for colorectal cancer.

In October 2005, we initiated a Phase 1, dose-escalation trial of a new formulation of Aroplatin in advanced solid malignancies and B cell lymphoma. In collaboration with the trial investigators, we have determined that the maximum tolerated dose of Aroplatin has been reached in this study. Based on this result, the trial has been closed. We have reviewed the results from this trial with our medical advisors and have decided not to pursue internal development of Aroplatin at the present time. However, we would consider licensing and/or co-development opportunities to advance the product.

## **Liquidity and Capital Resources**

We have incurred annual operating losses since inception, and we had an accumulated deficit of \$564.4 million as of September 30, 2009. We expect to incur significant losses over the next several years as we continue our clinical trials, apply for regulatory approvals, prepare for commercialization, and continue development of our technologies. Since our inception, we have financed our operations primarily through the sale of equity and convertible notes, interest income earned on cash, cash equivalents, and short-term investment balances, and debt provided through secured lines of credit. From our inception through September 30, 2009, we have raised aggregate net proceeds of \$494.8 million through the sale of common and preferred stock, the exercise of stock options and warrants, proceeds from our employee stock purchase plan, and the issuance of convertible notes, and borrowed \$20.5 million under two credit facilities. As of September 30, 2009, we had debt outstanding of \$51.0 million in principal, including \$30.8 million in principal of our 2006 Notes and \$20.0 million in principal of our 2005 Notes, but subject to redemption at the option of the holders or us beginning February 1, 2012.

Based on our current plans and activities, we anticipate that our net cash burn (defined as cash used in operating activities plus capital expenditures and dividend payments) will be approximately \$25 million for the year ending December 31, 2009. We continue to support and develop our QS-21 partnering collaborations, with the goal of generating royalties from this product in 2011 or thereafter.

We believe that, based on our current plans and activities, our working capital resources at September 30, 2009, anticipated revenues, and the estimated proceeds from our license, supply, and collaborative agreements will be sufficient to satisfy our liquidity requirements into 2011. We closely monitor our cash needs. We continue to monitor the likelihood of success of our key initiatives and are prepared to discontinue funding of such activities if they do not prove to be commercially feasible. In addition, we will continue to adjust other spending as needed in order to preserve liquidity. We expect to attempt to raise additional funds in advance of depleting our current funds. In order to fund our operations through 2011 and beyond, we will need to contain costs and raise additional funds. We may attempt to raise additional funds by: (1) licensing technologies or products to one or more collaborative partners, (2) renegotiating license and/or supply agreements with current collaborative partners, (3) completing an outright sale of assets, (4) securing additional debt financing, and/or (5) selling additional equity securities. Our ability to successfully enter into any such arrangements is uncertain, and if funds are not available, or not available on terms acceptable to us, we may be required to revise our planned clinical trials, other development activities, capital expenditures, and/or the scale of our operations. As noted above, we expect to attempt to raise additional funds in advance of depleting our current funds; however, we may not be able to raise funds or raise amounts sufficient to meet the long-term needs of the business. Satisfying long-term liquidity needs may require the successful commercialization of Oncophage and/or one or more partnering arrangements for Oncophage, successful commercialization of vaccines containing QS-21 under development by our licensees, and potentially successful commercialization of other product candidates, and will require additional capital, as discussed above. Please see the Forward-Looking Statements section and the risks highlighted under Part II-Item 1A. Risk Factors of this Quarterly Report on Form 10-Q.

Our future cash requirements include, but are not limited to, efforts to commercialize Oncophage in Russia and other jurisdictions we are currently exploring, as well as supporting our clinical trial and regulatory efforts and continuing our other research and development programs. Since inception, we have entered into various agreements with institutions and clinical research organizations to conduct and monitor our current clinical studies. Under these agreements, subject to the enrollment of patients and performance by the applicable institution of certain services, we have estimated our payments to be \$46.8 million over the term of the studies. Through September 30, 2009, we have expensed \$46.2 million

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as research and development expenses and \$46.0 million has been paid related to these clinical studies. The timing of expense recognition and future payments related to these agreements is subject to the enrollment of patients and performance by the applicable institution of certain services.

We have also entered into sponsored research agreements related to our product candidates that required payments of \$6.5 million, all of which has been paid as of September 30, 2009. We plan to enter into additional agreements, and we anticipate significant additional expenditures will be required to advance our clinical trials, apply for regulatory approvals, continue development of our technologies, and bring our product, Oncophage, and our product candidates to market. Part of our strategy is to develop and commercialize some of our product candidates by continuing our existing collaborative arrangements with academic and collaborative partners and licensees and by entering into new collaborations. As a result of our collaborative agreements, we will not completely control the efforts to attempt to bring those product candidates to market. We have various agreements, for example, with collaborative partners and/or licensees, which allow the use of our QS-21 adjuvant in numerous vaccines. These agreements grant exclusive worldwide rights in some fields of use and co-exclusive or non-exclusive rights in others. These agreements generally

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provide us with rights to manufacture and supply QS-21 to the collaborative partner or licensee and also call for royalties to be paid to us on future sales of licensed vaccines that include QS-21, which may or may not be achieved. Significant investment in manufacturing capacity could be required if we were to retain our manufacturing and supply rights.

Our cash, cash equivalents, and short-term investments at September 30, 2009 were \$34.0 million, a decrease of \$454,000 from December 31, 2008.

As part of our private placement agreements entered into in 2008 and 2009, we agreed to register the shares of common stock issued in the equity sales, and the shares of common stock underlying the warrants issued to the investors, with the SEC within contractually specified time periods. We have also agreed to use our best efforts to keep the registration statements continuously effective. If we are unable to keep the registration statements continuously effective in accordance with the terms of the private placement agreements, we are subject to liquidated damages of up to a maximum of 10% of the aggregate purchase price paid by the investors, or \$4.6 million.

During the nine months ended September 30, 2009, the increase in cash and cash equivalents was primarily due to the net cash provided by financing activities of \$17.8 million for the nine months ended September 30, 2009. During the nine months ended September 30, 2009, we raised net proceeds from private placements of \$18.6 million and we repurchased \$1.0 million of our 2005 Notes for \$255,000. Adding to our increase in cash and cash equivalents is our net cash provided by investing activities for the nine months ended September 30, 2009 of \$7.3 million as compared to \$5.9 million used in investing activities for the same period in 2008. During the nine months ended September 30, 2009, we had \$5.0 million of net maturities of short-term securities compared with net purchases of short-term securities of \$5.8 million during the nine months ended September 30, 2008. In addition, during 2009 we received \$2.3 million as payment on a receivable from the 2008 assignment of certain patent applications.

Net cash used in operating activities for the nine months ended September 30, 2009 and 2008 was \$20.6 million and \$23.7 million, respectively. We continue to support and develop our QS-21 partnering collaborations, with the goal of generating royalties from this product in 2011 or thereafter. Our future ability to generate cash from operations will depend on achieving regulatory approval of our product candidates, and market acceptance of Oncophage and our product candidates, achieving benchmarks as defined in existing collaborative agreements, and our ability to enter into new collaborations. Please see the **Forward-Looking Statements** section and the risks highlighted under Part II-Item 1A. **Risk Factors** of this Quarterly Report on Form 10-Q.

Effective July 19, 2002, we sublet part of our Framingham facility to GTC Biotherapeutics, Inc. ( **GTC** ), and we have leased related leasehold improvements and equipment under agreements that were to expire on December 31, 2006. GTC exercised its option to extend this lease until September 2010. Under the terms of our original lease, we are obligated to pay our landlord approximately 7% of our rental income. Effective March 17, 2004, we sublet an additional part of our Framingham facility to PP Manufacturing, whose lease also expires in September 2010. We are contractually entitled to receive base rental payments aggregating approximately \$295,000 during the remainder of 2009 and \$900,000 in 2010. The collection of this income, however, is subject to uncertainty.

We are currently involved in certain legal proceedings as detailed in Note E of the notes to our unaudited condensed consolidated financial statements. While we currently believe that the ultimate outcome of any of these proceedings will not have a material adverse effect on our financial position, results of operations, or liquidity, litigation is subject to inherent uncertainty. Furthermore, litigation consumes both cash and management attention.

## **Recent Accounting Pronouncements**

In June 2009, the Financial Accounting Standards Board ( **FASB** ) issued the Accounting Standards Codification ( **ASC** ) as the single source of authoritative U.S. generally accepted accounting principles ( **GAAP** ) recognized by the FASB to be applied by nongovernmental entities in preparation of financial statements in conformity with U.S. GAAP. While the adoption of the ASC as of September 30, 2009 changes how we reference accounting standards, the adoption did not have an impact on our financial position, results of operations, or cash flows.

In December 2007, the FASB issued authoritative guidance that expands the types of transactions or other events that will qualify as business combinations and requires that all business combinations will result in all assets and liabilities of the acquired business being recorded at their fair values, with limited exceptions. The authoritative guidance also requires, among other provisions, that certain contingent assets and liabilities will be recognized at their fair values on the acquisition date. An acquirer will also recognize contingent consideration at its fair value on the acquisition date and, for certain arrangements, changes in fair value will be recognized in earnings until the contingency is settled. Under this guidance acquisition-related transaction and restructuring costs will be expensed rather than treated as part of the cost of the acquisition and included in the amount recorded for assets acquired. This authoritative guidance is required to be applied prospectively to business combinations for which the acquisition is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. The adoption

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of this authoritative guidance did not have an impact on our financial position or results of operations.

In December 2007, the FASB issued authoritative guidance, which is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008, that governs the accounting for and reporting of noncontrolling interests in partially owned consolidated subsidiaries and the loss of control in subsidiaries. The adoption of this authoritative guidance did not have an impact on our financial position or results of operations.

In March 2008, the FASB issued authoritative guidance, which is effective for fiscal years, and interim periods within those fiscal years, beginning on or after November 15, 2008, that is intended to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity's financial position, financial performance and cash flows. The adoption of this authoritative guidance did not have an impact on our financial position or results of operations but required additional disclosure (see Note J to our unaudited condensed consolidated financial statements).

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In May 2008, the FASB issued revised authoritative guidance, which is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2008, that specifies that issuers of convertible debt instruments that may be settled in cash upon conversion should separately account for the liability and equity components in a manner that will reflect the entity's nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. We adopted this revised guidance as of January 1, 2009 and the effect on our consolidated financial statements is discussed in Note I to our unaudited condensed consolidated financial statements.

In June 2008, the FASB ratified revised guidance, which is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, that defines when adjustment features within contracts are considered to be equity-indexed. We adopted this guidance, which is applicable to our 2006 Notes due to the provisions contained therein that protect the holders from declines in our stock price, as of January 1, 2009. This guidance is applied prospectively, with a cumulative effect adjustment recorded to accumulated deficit as of January 1, 2009, as if the revised guidance had been applied to the 2006 Notes since their issuance. See Note I to our unaudited condensed consolidated financial statements for additional information as to the effect of the adoption of this guidance.

In April 2009, the FASB issued revised guidance requiring an acquirer to recognize at the acquisition date the fair value of an asset acquired or liability assumed in a business combination that arises from a contingency, if the acquisition-date fair value can be determined during the measurement period. This revised guidance is effective for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. This revised guidance may impact our accounting for future business combinations, if any.

In April 2009, the FASB also issued revised guidance with respect to estimating fair value when the volume and level of activity for the asset or liability have significantly decreased. This revised guidance also focuses on identifying circumstances that indicate a transaction is not orderly. The revised guidance emphasizes that even if there has been a significant decrease in the volume and level of activity for the asset or liability and regardless of the valuation technique(s) used, the objective of a fair value measurement remains the same. This guidance is effective for interim and annual reporting periods ending after June 15, 2009, and is to be applied prospectively with early adoption permitted for periods ending after March 15, 2009. The adoption of this guidance did not have an impact on our consolidated financial statements.

In April 2009, the FASB issued revised guidance amending the other-than-temporary impairment guidance for debt securities to make the guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. This revision does not amend existing recognition and measurement guidance related to other-than-temporary impairments of equity securities. This guidance is effective for interim and annual reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. The adoption of this revised guidance did not have an impact on our consolidated financial statements.

In April 2009, the FASB issued revised guidance to require disclosures about the fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. This revised guidance also requires those disclosures in summarized financial information at interim reporting periods. This authoritative guidance is effective for interim reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. The adoption of this authoritative guidance did not have an impact on our financial position or results of operations but required additional disclosure (see Notes I and J to our unaudited condensed consolidated financial statements).

In May 2009, the FASB issued authoritative guidance establishing general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued. This guidance also requires entities to disclose the date through which subsequent events were evaluated as well as the rationale for why that date was selected. This guidance is effective for interim and annual periods ending after June 15, 2009. The adoption of this guidance did not have an impact on our financial position or results of operations. We evaluated all events or transactions that occurred after September 30, 2009 up through November 9, 2009, the date our financials were issued. During this period, we did not have any material recognized or nonrecognized subsequent events.

In June 2009, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 166, *Accounting for Transfers of Financial Assets* (SFAS No. 166). SFAS No. 166 amends SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities* (SFAS No. 140), by removing the concept of a qualifying special-purpose entity from SFAS No. 140 and removing the exception from applying FASB Interpretation No. 46, *Consolidation of Variable Interest Entities (revised December 2003)* (FIN No. 46R) to variable interest entities that are qualifying special-purpose entities. It also modifies the financial-components approach used in SFAS No. 140. SFAS No. 166 is effective for transfers of financial assets occurring on or after January 1, 2010. The adoption of SFAS No. 166 may impact the accounting for future transactions, if any.

In June 2009, the FASB issued revised guidance which amends the guidelines for determining the existence of a variable interest entity and the related primary beneficiary. This revised guidance also requires ongoing reassessments of whether an enterprise is the primary beneficiary of a

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variable interest entity. The provisions of this guidance are effective for annual periods beginning after November 15, 2009, with early adoption prohibited. We do not expect the adoption of the provisions of this revised guidance to have a significant impact on our consolidated financial statements.

In October 2009, the FASB revised authoritative guidance on multiple-deliverable revenue arrangements providing a greater ability to separate and allocate arrangement consideration in a multiple-element revenue arrangement by requiring the use of estimated selling price to allocate arrangement consideration, thereby eliminating the use of the residual method of allocation. The revised



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guidance also requires expanded qualitative and quantitative disclosures surrounding multiple-deliverable revenue arrangements. This guidance is effective for fiscal years beginning after June 15, 2010 and may be applied retrospectively or prospectively for new or materially modified arrangements. Early adoption is permitted. We will evaluate the impact, if any, of this guidance on revenue transactions that we may enter into in the future.

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

In the normal course of business, we are exposed to fluctuations in interest rates as we seek debt financing and invest excess cash. We are also exposed to foreign currency exchange rate fluctuation risk related to our transactions denominated in foreign currencies. We do not currently employ specific strategies, such as the use of derivative instruments or hedging, to manage these exposures. Our currency exposures vary, but are primarily concentrated in the euro and the ruble. There has been no material change with respect to our interest rate and foreign currency exposures or our approach toward those exposures, as described in our Annual Report on Form 10-K for the year ended December 31, 2008. However, commercialization of Oncophage in Russia and possible commercialization of Oncophage in other locations outside of the United States could result in increased foreign currency exposure.

We had cash, cash equivalents, and short-term investments at September 30, 2009 of \$34.0 million, which are exposed to the impact of interest rate changes, and our interest income fluctuates as interest rates change. Due to the short-term nature of our investments in money market funds, the carrying value approximates the fair value of these investments at September 30, 2009; however, we are subject to investment risk.

We invest our cash, cash equivalents, and short-term investments in accordance with our Investment Policy. The primary objectives of our Investment Policy are to preserve principal, maintain liquidity to meet operating needs, and maximize yields. We review our Investment Policy annually and amend it as deemed necessary. Currently, the Investment Policy prohibits investing in any structured investment vehicles and asset-backed commercial paper. Although our investments are subject to credit risk, our Investment Policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer, or type of investment. Our investments are also subject to interest rate risk and will decrease in value if market interest rates increase. However, due to the conservative nature of our investments and relatively short duration, interest rate risk is mitigated. We do not invest in derivative financial instruments. Accordingly, we do not believe that there is currently any material market risk exposure with respect to derivatives or other financial instruments that would require disclosure under this item.

### **Item 4. *Controls and Procedures*** **Evaluation of Disclosure Controls and Procedures**

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) and Rule 15d-15(e) promulgated under the Securities Exchange Act of 1934 (the "Securities Exchange Act"). Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective and were designed to ensure that information we are required to disclose in the reports that we file or submit under the Securities Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure, and is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. It should be noted that any system of controls is designed to provide reasonable, but not absolute, assurances that the system will achieve its stated goals under all reasonably foreseeable circumstances.

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

During the quarter ended September 30, 2009, there was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act) that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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### **PART II OTHER INFORMATION**

#### **Item 1. Legal Proceedings**

Antigenics, our Chairman and Chief Executive Officer, Garo H. Armen, Ph.D., and two investment banking firms that served as underwriters in our initial public offering have been named as defendants in a federal civil class action lawsuit pending in the United States District Court for the Southern District of New York. Substantially similar actions were filed concerning the initial public offerings for more than 300 different issuers, and the cases were coordinated as *In re Initial Public Offering Securities Litigation*, 21 MC 92 for pre-trial purposes. The suit alleges that the brokerage arms of the investment banking firms charged secret excessive commissions to certain of their customers in return for allocations of our stock in the offering. The suit also alleges that shares of our stock were allocated to certain of the investment banking firms customers based upon agreements by such customers to purchase additional shares of our stock in the secondary market. Dr. Armen has been dismissed without prejudice from the lawsuit pursuant to a stipulation. In June 2004, a stipulation of settlement and release of claims against the issuer defendants, including us, was submitted to the Court for approval. The Court preliminarily approved the settlement in August 2005. In December 2006, the appellate court overturned the certification of classes in six test cases that were selected by the underwriter defendants and plaintiffs in the coordinated proceedings. Class certification had been one of the conditions of the settlement. Accordingly, on June 25, 2007, the Court entered an order terminating the proposed settlement based on a stipulation among the parties to the settlement. Plaintiffs have filed amended master allegations and amended complaints and moved for class certification in the six test cases, which the defendants in those cases have opposed. On March 26, 2008, the Court largely denied the defendants' motion to dismiss the amended complaints. The parties have reached a global settlement of the litigation. Under the settlement, the insurers will pay the full amount of settlement share allocated to the defendants, and the defendants will bear no financial liability. The company defendants, as well as the officer and director defendants who were previously dismissed from the action pursuant to tolling agreements, will receive complete dismissals from the case. On October 5, 2009, the Court entered an order granting final approval of the settlement. Certain objectors are seeking to appeal. If for any reason the settlement does not become effective, we believe we have meritorious defenses to the claims and intend to defend the action vigorously. We are unable to predict the likelihood of an unfavorable outcome or estimate our potential liability, if any.

We may currently be a party, or may become a party, to other legal proceedings as well. The ultimate outcome of any such proceedings is subject to inherent uncertainty. Furthermore, litigation consumes both cash and management attention.

#### **Item 1A. Risk Factors**

Our future operating results could differ materially from the results described in this Quarterly Report on Form 10-Q due to the risks and uncertainties described below. We cannot assure investors that our assumptions and expectations will prove to have been correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. See Forward-Looking Statements on page 12 of this Quarterly Report on Form 10-Q. Factors that could cause or contribute to such differences include those factors discussed below.

#### **Risks Related to our Business**

*If we incur operating losses for longer than we expect, or we are not able to raise additional capital, we may be unable to continue our operations, or we may become insolvent.*

From our inception through September 30, 2009, we have generated net losses totaling \$564.4 million. Our net losses for the nine months ended September 30, 2009 and the years ended December 31, 2008, 2007, and 2006 were \$32.2 million, \$30.8 million, \$37.9 million, and \$52.8 million, respectively. We expect to incur significant losses over the next several years as we continue research and clinical development of our technologies, apply for regulatory approvals, and pursue commercialization efforts and related activities. Furthermore, our ability to generate cash from operations is dependent on the success of our licensees and collaborative partners, as well as the likelihood and timing of new strategic licensing and partnering relationships and/or successful commercialization of Oncophage and our various product candidates. If we incur operating losses for longer than we expect and/or we are unable to raise additional capital, we may become insolvent and be unable to continue our operations.

On September 30, 2009, we had \$34.0 million in cash, cash equivalents, and short-term investments. We believe that, based on our current plans and activities, our working capital resources at September 30, 2009, combined with anticipated revenues, and the estimated proceeds from our license, supply, and collaborative agreements will be sufficient to satisfy our liquidity requirements into 2011. We expect to attempt to raise additional funds in advance of depleting our current funds. For the nine months ended September 30, 2009, our average monthly cash used in

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operating activities was \$2.3 million. We do not anticipate significant capital expenditures during 2009.

As part of certain private placement agreements, we are required to maintain effective registration statements. If we are unable to keep the registration statements continuously effective in accordance with the terms of the private placement agreements, we are subject to liquidated damages penalties of up to a maximum of 10% of the aggregate purchase price paid by the original investors, or \$4.6 million.

Since our inception, we have financed our operations primarily through the sale of equity and convertible notes, interest income earned on cash, cash equivalents, and short-term investment balances, and debt provided through secured lines of credit. In order to finance future operations, we will be required to raise additional funds in the capital markets, through arrangements with collaborative partners, or from other sources.

Additional financing may not be available on favorable terms, or at all. If we are unable to raise additional funds when we need

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them, we will be required to delay, reduce, or eliminate some or all of our development, commercialization and clinical trial programs, including those related to Oncophage. We also may be forced to license or sell technologies to others under agreements that allocate to third parties substantial portions of the potential value of these technologies. We may also be unable to continue our operations, or we may become insolvent.

The United States economy, and possibly the global economy, has been experiencing a recession. While the ultimate outcome cannot be predicted, this may have a material adverse effect on our liquidity and financial condition, particularly if our ability to raise additional funds is impaired. The ability of potential patients and/or health care payers to pay for Oncophage treatments could also be adversely impacted, thereby limiting our potential revenue. In addition, any negative impacts from the deterioration in the credit markets and related financial crisis on our collaborative partners could limit potential revenue from our product candidates.

### ***We have significant long-term debt, and we may not be able to make interest or principal payments when due.***

As of September 30, 2009, the principal portion of our total long-term debt, excluding the current portion, was \$50.8 million. Our 2005 Notes do not restrict our ability or the ability of our subsidiaries to incur additional indebtedness, including debt that effectively ranks senior to the 2005 Notes. On each of February 1, 2012, February 1, 2015, and February 1, 2020, holders may require us to purchase their notes for cash equal to 100% of the principal amount of the notes, plus any accrued and unpaid interest. Holders may also require us to repurchase their notes upon a fundamental change, as defined, at a cash price equal to 100% of the principal amount of the notes to be repurchased, plus any accrued and unpaid interest, and in some cases, an additional make-whole premium.

At maturity of our 2006 Notes, we may elect to repay the outstanding balance in cash or in common stock, subject to certain limitations. In no event will any of the note holders be obligated to accept equity that would result in them owning in excess of 9.99% of our outstanding common stock at any given time in connection with any conversion, redemption, or repayment of these notes. The 2006 Note agreements include material restrictions on our incurrence of debt and liens while these notes are outstanding, as well as other customary covenants.

Our ability to satisfy our obligations will depend upon our future performance, which is subject to many factors, including the factors identified in this Risk Factors section and other factors beyond our control. If we are not able to generate sufficient cash flow from operations in the future to service our indebtedness, we may be required, among other things, to:

seek additional financing in the debt or equity markets;

refinance or restructure all or a portion of our indebtedness;

sell, out-license, or otherwise dispose of assets; and/or

reduce or delay planned expenditures on research and development and/or commercialization activities.

Such measures might not be sufficient to enable us to make principal and interest payments. In addition, any such financing, refinancing, or sale of assets might not be available on economically favorable terms, if at all.

To date, we have had negative cash flows from operations. For the nine months ended September 30, 2009 and the years ended December 31, 2008, 2007, and 2006, net cash used in operating activities was \$20.6 million, \$28.9 million, \$26.7 million, and \$44.9 million, respectively. Excluding our 2006 Notes, which mature in 2011 and for which we may elect to pay the interest in cash or additional notes, at our option, and for which the outstanding balance at maturity may be paid in cash or in common stock, subject to certain limitations, and assuming no additional interest-bearing debt is incurred and no additional notes are converted, redeemed, repurchased, or exchanged, our cash interest payments will be \$1.6 million during 2009 and \$1.0 million annually thereafter until maturity.

***Several factors could delay or prevent the successful commercial launch of Oncophage in Russia. In addition, we do not expect to generate significant revenue from sales of Oncophage in Russia for several months, if ever.***

In April 2008, the Russian Ministry of Public Health issued a registration certificate for the use of Oncophage for the treatment of kidney cancer patients at intermediate risk for disease recurrence and, in September 2008, the FDA granted the necessary permission to allow for the export of

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Oncophage from the United States to Russia. The Russian registration was our first product approval from a regulatory authority.

We have obtained an import/export license from the Russian Ministry of Industry and Trade, but prior to commercial launch we, or our distributors, must also complete a number of other post-approval activities. Since Oncophage can only be manufactured from a patient's own tumor, patients will need to be diagnosed, and their tumors will need to be removed and sent to our manufacturing facility for vaccine to be prepared, released, and then returned to the site for patient administration. Complexities unique to the logistics of commercial products may delay shipments and limit our ability to move commercial product in an efficient manner without incident. In addition, if we are unable to establish and execute on successful local distribution arrangements including favorable pricing and payment terms, and/or implement appropriate logistical processes for distribution of Oncophage, our commercialization efforts would be adversely affected.

Even if we have a successful completion of the logistical and regulatory requirements for Russian launch, the amount of revenue generated from the sale of Oncophage in Russia will depend on, among other things, identifying sources of reimbursement and obtaining adequate reimbursement, including from national or regional funds, and physician and patient assessments of the benefits and cost-effectiveness of Oncophage. If we are unsuccessful in obtaining substantial reimbursement for Oncophage from national or regional funds, we will have to rely on private-pay for the foreseeable future, which may delay or reduce our launch efforts because the ability and willingness of patients to pay is unclear. In addition, cost-containment measures by third parties may prevent

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us from becoming profitable. Because we have limited resources and minimal sales and marketing experience, commercial launch of Oncophage may be slow. Furthermore, we may experience significant delays in the receipt of payment for Oncophage, or an inability to collect payments at all.

On October 20, 2009 the CHMP of the EMEA informed us at an oral hearing to anticipate a negative opinion on our marketing authorization application ( MAA ) we submitted to the EMEA in October 2008. We are currently evaluating our options to determine the best path forward for Oncophage. We do not know what impact, if any, this opinion will have on our Russian activities. If we continue to pursue a marketing authorization application for Oncophage with the EMEA, there is a high level of uncertainty regarding the probability and timing of a favorable outcome.

***If we fail to obtain adequate levels of reimbursement for Oncophage, our product candidates, or the product candidates of our licensees or collaborators, there may be no commercially viable market for these products, or the commercial potential of these products may be significantly limited.***

Public and private insurance programs may determine that Oncophage, our product candidates, or the product candidates of our licensees or collaborative partners do not come within a category of items and services covered by their insurance plans. In Russia, Europe, and other countries outside the United States, government-sponsored health care systems typically pay a substantial share of health care costs, and they may regulate reimbursement levels of our products to control costs. Government and private third-party payers are increasingly challenging the prices charged for medical products and services, and increasingly attempting to limit and/or regulate the reimbursement for medical products. In many of the markets where we or our collaborative partners would commercialize a product following regulatory approval, the prices of pharmaceutical products are subject to price controls by various mechanisms. Russia is an evolving market and regulatory, legal, and commercial structures are less predictable than in more mature markets. In addition, the reimbursement system in Russia is changing rapidly and has experienced serious funding and administrative problems in its national and regional reimbursement programs. For example, the program known by the Russian acronym of DLO, which was established in January 2005 to provide free-of-charge prescriptions to certain Russians, has substantially delayed payments and covered fewer drugs recently. In addition, the Russian government is attempting to reduce coverage for drugs produced outside of Russia, as they tend to cost more than drugs produced in Russia. Furthermore, it is possible that reimbursement for cancer drugs and other therapeutic areas will not be covered by a newly created system, which may result in uncertainties regarding levels of reimbursement. Drug reimbursement in Russia could continue to undergo change. There can be no assurance regarding the timing, scope, or availability of reimbursement in Russia for Oncophage. In addition, we do not know the impact, if any, that the verbal opinion received on our MAA in Europe will have on our reimbursement efforts. If we are unsuccessful in obtaining substantial reimbursement for Oncophage from national or regional funds, we will have to rely on private-pay for the foreseeable future, which may delay or prevent our launch efforts, because the ability and willingness of patients to pay for the product is unclear.

It is possible that there will be substantial delays in obtaining coverage of Oncophage, our product candidates, or the product candidates of our licensees or collaborative partners, if at all, and that, if coverage is obtained, there may be significant restrictions on the circumstances in which there would be reimbursement. Where government or insurance coverage is available, there may be prohibitive levels of patient coinsurance, making products unaffordable, or limits on the payment amount, which could have a material adverse effect on sales. If we are unable to obtain or retain adequate levels of reimbursement from government or private health plans, our or our collaborative partners' ability to sell products will be adversely affected. We are unable to predict what impact any future regulation or third-party payer initiatives relating to reimbursement will have on sales. Healthcare reform that may emerge from current policy debate may result in deleterious pricing and potential price controls on pharmaceutical and biotech products in the United States, Europe, and elsewhere.

***If we fail to comply with regulatory requirements in the countries in which we conduct our business, if these regulatory requirements change, or if we experience unanticipated regulatory problems, our commercial launch of Oncophage could be prevented or delayed, or Oncophage could be subjected to restrictions, or be withdrawn from the market, or some other action may be taken that may be adverse to our business.***

Regulatory authorities generally approve products for particular indications. If an approval is for a limited indication, this limitation reduces the size of the potential market for that product. Product approvals, once granted, are subject to continual review and periodic inspections by regulatory authorities. Later discovery of previously unknown problems or safety issues and/or failure to comply with applicable regulatory requirements can result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to renew marketing applications, complete withdrawal of a marketing application, and/or criminal prosecution. Such regulatory enforcement could have a direct and negative impact on the product for which approval is granted, but also could have a negative impact on the approval of any pending applications for marketing approval of new drugs or supplements to approved applications.

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In addition, our operations and marketing practices are subject to regulation and scrutiny by the United States government, as well as governments of any other countries in which we do business or conduct activities. Because we are a company operating in a highly regulated industry, regulatory authorities could take enforcement action against us in connection with our business and marketing activities for various reasons.

For example, our marketing and sales, labeling, and promotional activities in Russia are subject to local regulations. If we fail to comply with regulations prohibiting the promotion of products for non-approved indications or products for which marketing approval has not been granted, regulatory authorities could bring enforcement actions against us that could inhibit our marketing capabilities, as well as result in penalties. In addition, the United States Foreign Corrupt Practices Act prohibits U.S. companies and their representatives from offering, promising, authorizing, or making payments to foreign officials for the purpose of obtaining or retaining business abroad. Failure to comply with domestic or foreign laws, knowingly or unknowingly, could result in various adverse consequences, including possible delay in approval or refusal to approve a product, recalls, seizures, withdrawal of an

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approved product from the market, exclusion from government health care programs, imposition of significant fines, injunctions, and/or the imposition of civil or criminal sanctions against us and/or our officers or employees.

From time to time, new legislation is passed into law that could significantly change the statutory provisions governing the approval, manufacturing, and marketing of products regulated by the FDA and other global health authorities. Additionally, regulations and guidance are often revised or reinterpreted by health agencies in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted, or whether regulations, guidance, or interpretations will change, and what the impact of such changes, if any, may be.

***We may not be able to obtain approval to make Oncophage available in countries other than Russia.***

Oncophage is currently only approved for marketing in Russia for the treatment of kidney cancer patients at intermediate risk for disease recurrence. In October 2008, we submitted a MAA to the EMEA requesting conditional authorization of Oncophage in earlier-stage, localized kidney cancer. On October 20, 2009 the CHMP of the EMEA informed us at an oral hearing to anticipate a negative opinion on this MAA. We are currently evaluating our options to determine the best path forward for Oncophage. Conditional authorization, a relatively new provision, is reserved for products intended to treat serious and life-threatening diseases where a high unmet medical need currently exists. Conditional authorization allows for the commercialization of a product with post-approval commitments associated with the requirement to provide comprehensive clinical information about the product's efficacy and safety profile. If we continue to pursue a marketing authorization application for Oncophage with the EMEA, there is a high level of uncertainty regarding the probability and timing of a favorable outcome. In addition, even if we continue this pursuit, Oncophage may not achieve conditional approval in Europe because we may not successfully address issues associated with post-hoc analysis, subgroup analysis, lack of immunological data, product characterization, or other issues that may be of concern to the EMEA.

The probability and timing of submissions and/or approval in any jurisdiction or indication for this product is uncertain. The FDA has indicated that our Phase 3 clinical trials of Oncophage cannot, by themselves, support BLA filings in the studies' indications (renal cell carcinoma and metastatic melanoma). The signals and trends observed in the Phase 3 renal cell carcinoma and melanoma trials of Oncophage are based on data analysis of subgroups of patients, some of which were not pre-specified. While the subgroup data might be suggestive of treatment effect, under current regulatory guidelines the results cannot be expected, alone, to support registration or approval of Oncophage in the United States, and our existing data may not support registration or approval in other territories outside of Russia, including in Europe. Any additional studies may take years to complete and may fail to support regulatory filings for many reasons. In addition, Oncophage is a novel therapeutic cancer vaccine that is patient-specific, meaning it is derived from the patient's own tumor. The FDA and foreign regulatory agencies, including the EMEA, which is responsible for product approvals in Europe, and Health Canada, which is responsible for product approvals in Canada, have relatively little experience in reviewing this novel class of patient-specific oncology therapies. Therefore, Oncophage may experience a long regulatory review process and high development costs, either of which could delay or prevent our commercialization efforts.

***Risks associated with doing business internationally could negatively affect our business.***

With the registration of Oncophage in Russia, we have begun to focus our efforts on the commercial launch of this product. However, Russia is an evolving market and regulatory, legal, and commercial structures are less predictable than in more mature markets. This unpredictability, as well as potential geopolitical instability in the Russian region, could negatively impact the regulatory and/or commercial environment there, which in turn could have an adverse effect on our business.

In addition, various other risks associated with foreign operations may impact our success. Possible risks include fluctuations in the value of foreign and domestic currencies, disruptions in the import, export, and transportation of patient tumors and our product, the product and service needs of foreign customers, difficulties in building and managing foreign relationships, the performance of our licensees or collaborators, and unexpected regulatory, economic, or political changes in foreign markets.

Our financial position, results of operations, and cash flows can be affected by fluctuations in foreign currency exchange rates, primarily for the euro and the ruble. Movement in foreign currency exchange rates could cause revenue or clinical trial costs to vary significantly in the future and may affect period-to-period comparisons of our operating results. Historically, we have not hedged our exposure to these fluctuations in exchange rates.

***Our commercial operations experience and resources are limited and need to be developed or acquired. If we fail to do so, our revenues may be limited or nonexistent. In addition, we may be required to incur significant costs and devote significant efforts to augment our existing capabilities.***



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As we have limited experience with commercial operations, it may be difficult to accurately estimate our costs. We currently do not have employees, manufacturing, or business operations facilities outside of the United States. As we prepare for the commercial launch of Oncophage in Russia, and in the event we are able to launch Oncophage in other territories, we will rely significantly on consultants, partners, and other third parties to conduct our sales, marketing, and distribution operations. If these third parties are unable to fulfill their obligations, our commercial launch of Oncophage could be delayed or prevented. If in the future we elect to perform sales, marketing, and distribution functions ourselves, we will face a number of additional risks, including the need to recruit experienced marketing and sales personnel, or incur significant expenditures. In addition, we may need to compete with other companies that have more experienced and better-funded operations. Where we have licensed our products to third-party collaborators or licensees, we will be dependent on their commercial operations, sales and marketing expertise and resources, and any revenues we receive from those products will depend primarily on the sales and marketing efforts of others.

For Oncophage, we need to develop specialized commercial operations to manage patient-specific ordering, tracking, and control. There are few companies that have developed this expertise and we do not know whether we will be able to establish commercial operations or enter into marketing and sales agreements with others on acceptable terms, if at all.

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*Our competitors in the biotechnology and pharmaceutical industries may have superior products, manufacturing capability, and/or selling and marketing expertise.*

Our business and the products in development by our collaborative partners may fail because of intense competition from major pharmaceutical companies and specialized biotechnology companies engaged in the development of product candidates directed at cancer, infectious diseases and degenerative disorders. Several of these companies have products that utilize technologies similar to Oncophage and/or patient-specific medicine techniques, such as Dendreon, Accentia, Oxford BioMedica and its partner Sanofi-Aventis.

There is no guarantee that we will be able to compete with potential future products being developed by our competitors. More specifically, Oncophage may compete with therapies currently in development for non-metastatic renal cell carcinoma, such as Willex AG's Rencarex (WX-G250), which is in Phase 3 clinical trials. Additionally, sorafenib and sunitinib, which are approved for advanced renal cell carcinoma, are being studied in non-metastatic renal cell carcinoma, and other products that have been developed for metastatic renal cell carcinoma, such as temsirolimus, bevacizumab and pazopanib, may also be developed for non-metastatic renal cell carcinoma. As Oncophage is potentially developed in other indications, it will face additional competition in those indications. In addition, for Oncophage and all of our product candidates, prior to regulatory approval, we may compete for access to patients with other products in clinical development, with products approved for use in the indications we are studying, or with off-label use of products in the indications we are studying. We anticipate that we will face increased competition in the future as new companies enter markets we seek to address and scientific developments surrounding immunotherapy and other traditional cancer therapies continue to accelerate.

Our patent to purified QS-21 expired in most territories in 2008. Additional protection for our QS-21 proprietary adjuvant in combination with other agents is provided by our other patents. Our license and supply agreements for QS-21 typically provide royalties for at least 10 years after commercial launch independent of patent expiry. However, there is no guarantee that we will be able to collect royalties in the future.

We are aware of a saponin adjuvant called OPT-821 which is claimed to be identical to QS-21. OPT-821 was developed by Optimer Pharmaceuticals and is being used in ongoing cancer vaccine trials. Several other vaccine adjuvants are in development and could compete with QS-21 for inclusion in vaccines in development. These adjuvants include, but are not limited to, oligonucleotides, under development by Pfizer, Idera, Juvaris, and Dynavax, anti-CTLA-4 antibody, under development by Pfizer and Bristol-Myers Squibb, MF59 and SAF, under development by Novartis, IC31, under development by Intercell, and MPL, under development by GlaxoSmithKline (GSK). In addition, at least one company, CSL Limited, as well as academic institutions, are developing saponin adjuvants, including derivatives and synthetic formulations.

Many of our competitors, including large pharmaceutical companies, have greater financial and human resources and more experience than we do. Our competitors may:

commercialize their product candidates sooner than we commercialize our own;

develop safer or more effective therapeutic drugs or preventive vaccines and other therapeutic products;

implement more effective approaches to sales and marketing and capture some of our potential market share;

establish superior intellectual property positions;

discover technologies that may result in medical insights or breakthroughs, which render our drugs or vaccines obsolete, possibly before they generate any revenue; or

adversely affect our ability to recruit patients for our clinical trials.

*Manufacturing problems may cause product launch delays, unanticipated costs, or loss of revenue streams.*

If one of our product candidates or our licensees' product candidates nears marketing approval or is approved for sale, or if the demand for Oncophage is substantially greater than we anticipate, we may be required to manufacture substantially more product than we have been required to in the past. With higher manufacturing loads, we may experience higher manufacturing failure rates than we have in the past. We currently manufacture Oncophage in our Lexington, Massachusetts facility and we intend to continue using this facility to manufacture Oncophage to satisfy all demands for product. While we believe we will be able to cover all Oncophage demands in the near term, there is no guarantee that we will be able to meet any unanticipated increase in demand, and a failure to do so could adversely affect our business. Such demand may also limit our ability to manufacture Oncophage in support of clinical trials, and this could cause a delay or failure in our Oncophage programs. Manufacturing of Oncophage is complex, and various factors could cause delays or an inability to supply vaccine. Deviations in the processes controlling manufacture could result in production failures.

We can also manufacture other clinical products in our own manufacturing facility. This manufacturing facility has certain support areas that it shares with the Oncophage manufacturing areas. As we seek to make Oncophage available in other territories, the applicable regulatory bodies may require us to make our Oncophage manufacturing facility a single product facility. In such an instance, we would no longer have the ability to manufacture products such as AG-707 in our current facility. In order to prepare additional AG-707 to support future clinical trials, we would then have to manufacture or have manufactured this product in a good manufacturing practice ( GMP ) compliant facility.

Currently, we do not manufacture QS-21 in our own manufacturing facility, and we have given our two QS-21 licensees who have the most advanced clinical programs utilizing QS-21 the right to manufacture QS-21 themselves or through third party manufacturers. If these key licensees are unable to successfully manufacture or have manufactured QS-21, the commercialization of

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the product candidates being developed by such licensees could be delayed or prevented, and we could lose important potential future revenue streams. In addition, we continue to support other third party programs through the supply of QS-21 manufactured by our third party manufacturer. There is no guarantee that this third party manufacturer will continue to supply us in the future. In such an event, in order to continue to support such programs, we would need to engage another supplier or build internal capacity. Either of these options would require the investment of substantial funds and the recruitment of a qualified alternative manufacturer or internal personnel. In addition, we or our third party manufacturer(s), collaboration partners or licensees may never have the ability to manufacture commercial grade QS-21.

We currently rely upon and expect to continue to rely upon third parties, potentially including our collaborators or licensees, to produce materials required for product candidates, preclinical studies, clinical trials, and commercialization. A number of factors could cause production interruptions at our manufacturing facility or at our contract manufacturers, including equipment malfunctions, labor or employment retention problems, natural disasters, power outages, terrorist activities, or disruptions in the operations of our suppliers. Alternatively, there is the possibility we may have excess manufacturing capacity if product candidates do not progress as planned.

There are a limited number of contract manufacturers that are capable of manufacturing our product candidates. If we are unable to do so ourselves or to arrange for third-party manufacturing of these product candidates, or to do so on commercially reasonable terms, we may not be able to complete development of these product candidates or commercialize them ourselves or through our collaborative partners or licensees. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured products ourselves, including reliance on the third party for regulatory compliance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, and the possibility of termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

Manufacturing is also subject to extensive government regulation. Regulatory authorities must approve the facilities in which human health care products are produced. In addition, facilities are subject to ongoing inspections, and minor changes in manufacturing processes may require additional regulatory approvals, either of which could cause us to incur significant additional costs and lose revenue.

### ***The drug development and approval process is uncertain, time-consuming, and expensive.***

Clinical development, including preclinical testing and the process of obtaining and maintaining regulatory approvals for new therapeutic products, is lengthy, expensive, and uncertain. It also can vary substantially based on the type, complexity, and novelty of the product. We must provide regulatory authorities with preclinical and clinical data demonstrating that our product candidates are safe and effective before they can be approved for commercial sale. It may take us several years to complete our testing, and failure can occur at any stage of testing. Interim results of preclinical studies or clinical trials do not necessarily predict their final results, and acceptable results in early studies might not be seen in later studies. Any preclinical or clinical test may fail to produce results satisfactory to regulatory authorities for many reasons, including but not limited to study structure, conduct, failure to enroll a sufficient number of patients, and collectability of data. Preclinical and clinical data can be interpreted in different ways, which could delay, limit, or prevent regulatory approval. Negative or inconclusive results from a preclinical study or clinical trial, adverse medical events during a clinical trial, or safety issues resulting from products of the same class of drug could require a preclinical study or clinical trial to be repeated or cause a program to be terminated, even if other studies or trials relating to the program are successful. As of September 30, 2009, we have spent approximately 15 years and \$267.8 million on our research and development program in heat shock proteins for cancer.

We may not complete our planned preclinical studies or clinical trials on schedule or at all. We may not be able to confirm the safety and efficacy of our potential drugs in long-term clinical trials, which may result in further delays or failure to commercialize our product candidates. The timing and success of a clinical trial is dependent on enrolling sufficient patients in a timely manner, avoiding serious or significant adverse patient reactions, and demonstrating efficacy of the product candidate in order to support a favorable risk versus benefit profile, among other considerations. Because we rely on third-party clinical investigators and contract research organizations to conduct our clinical trials, we may encounter delays outside our control, particularly if our relationships with any third-party clinical investigators or contract research organizations are adversarial. The timing and success of our clinical trials, in particular, are also dependent on clinical sites and regulatory authorities accepting each trial's protocol, statistical analysis plan, product characterization tests, and clinical data. If we are unable to satisfy clinical sites or regulatory authorities with respect to such matters, including the specific matters noted above, or our clinical trials yield inconclusive or negative results, we will be required to modify or expand the scope of our clinical studies or conduct additional studies to support marketing approvals, or modify our development pipeline. In addition, regulatory authorities may request additional information or data that is not readily available. Delays in our ability to respond to such requests would delay, and failure to adequately address concerns would prevent, our commercialization efforts.

Also, we or regulatory authorities might further delay or halt our clinical trials for various reasons, including but not limited to:

we may fail to comply with extensive regulations;

a product candidate may not appear to be more effective than current therapies;

a product candidate may have unforeseen, undesirable, or significant adverse side effects, toxicities, or other characteristics;

we may fail to prospectively identify, or identify at all, the most appropriate patient populations and/or statistical analyses for inclusion in our clinical trials;

the time required to determine whether a product candidate is effective may be longer than expected;

we may be unable to adequately follow or evaluate patients after treatment with a product candidate;

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patients may die during a clinical trial because their disease is too advanced or because they experience medical problems that may not be related to the product candidate;

sufficient numbers of patients may not meet our eligibility criteria and/or enroll in our clinical trials and may withdraw from our clinical trials after they have enrolled; or

we may be unable to produce sufficient quantities of a product candidate to complete the trial.

Our existing Oncophage data may not support registration or approval for Oncophage in territories outside of Russia. Any additional studies may take years to complete and may fail to support regulatory filings for many reasons. In October 2008, we submitted a MAA to the EMEA, requesting conditional authorization of Oncophage in earlier-stage, localized kidney cancer. On October 20, 2009, the CHMP of the EMEA informed us at an oral hearing to anticipate a negative opinion on this MAA. We are currently evaluating our options to determine the best path forward for Oncophage in this territory. If we continue to pursue a marketing authorization application for Oncophage with the EMEA, there is a high level of uncertainty regarding the probability and timing of a favorable outcome. In addition, even if we continue this pursuit, Oncophage may not achieve conditional approval in Europe. Additionally, the FDA has indicated that our Phase 3 clinical trials of Oncophage cannot, by themselves, support BLA filings in the studies' indications (renal cell carcinoma and metastatic melanoma). The signals and trends observed in the Phase 3 renal cell carcinoma and melanoma trials of Oncophage are based on data analysis of subgroups of patients, some of which were not pre-specified. While the subgroup data might be suggestive of treatment effect, under current regulatory guidelines the results cannot be expected, alone, to support registration or approval of Oncophage in the United States. Furthermore, regulatory authorities, including the FDA and the EMEA, may have varying interpretations of our preclinical study and clinical trial data for our other product candidates, which could delay, limit, or prevent regulatory approval or clearance. Delays or difficulties in obtaining regulatory approvals or clearances for Oncophage and/or our product candidates may:

adversely affect the marketing of any products we or our licensees or collaborators develop;

impose significant additional costs on us or our licensees or collaborators;

diminish any competitive advantages that we or our licensees or collaborators may attain;

limit our ability to receive royalties and generate revenue and profits; and

adversely affect our business prospects and ability to obtain financing.

Delays or failures in our receiving regulatory approval for our product candidates in a timely manner may result in us having to incur additional development expense and subject us to having to secure additional financing. As a result, we will not be able to commercialize them in the timeframe anticipated, and our business will suffer.

***New data from our research and development activities and/or resource considerations could modify our strategy and result in the need to adjust our projections of timelines and costs of programs.***

Because we are focused on novel technologies, our research and development activities, including our preclinical studies and clinical trials, involve the ongoing discovery of new facts and the generation of new data, based on which we determine next steps for a relevant program. These developments are sometimes a daily occurrence and constitute the basis on which our business is conducted. We need to make determinations on an ongoing basis as to which of these facts or data will influence timelines and costs of programs. We may not always be able to make such judgments accurately, which may increase the costs we incur attempting to commercialize our product candidates. We monitor the likelihood of success of our initiatives and due to our limited resources we may need to discontinue funding of such activities if they do not prove to be commercially feasible. These issues are pronounced in our efforts to commercialize Oncophage, which represents an unprecedented approach to the treatment of cancer.

We may need to successfully address a number of technological challenges in order to complete development of our product candidates. Moreover, these product candidates may not be effective in treating any disease or may prove to have undesirable or unintended side effects, toxicities, or other characteristics that may preclude our obtaining regulatory approvals or prevent or limit commercial use.

***Failure to enter into significant collaboration agreements may hinder our efforts to develop and commercialize our product candidates and will increase our need to rely on other financing mechanisms, such as sales of securities, to fund our operations.***

We have been engaged in efforts to enter into collaborative agreements with one or more pharmaceutical or larger biotechnology companies to assist us with development and/or commercialization of our product candidates. If we are successful in entering into a collaborative agreement, we may not be able to negotiate agreements with economic terms similar to those negotiated by other companies. We may not, for example, obtain significant up-front payments or substantial royalty rates. If we fail to enter into collaboration agreements, our efforts to develop and/or commercialize our products or product candidates may be undermined. In addition, if we do not raise funds through collaboration agreements, we will need to rely on other financing mechanisms, such as sales of securities, to fund our operations. Sales of certain securities may substantially dilute the ownership of existing stockholders. If we are unable to complete the sale of such securities, we may become insolvent.

While we have been pursuing these business development efforts for several years, we have not entered into an agreement relating to the potential development or commercialization of Oncophage. Due to the announcements in March 2006 that part I of our Phase 3 trial in renal cell carcinoma did not achieve its primary endpoint in the intent to treat population, and in October 2009 that the CHMP has provided a verbal negative opinion on our MAA, and because companies may be skeptical regarding the potential success of a patient-specific product candidate, many companies may be unwilling to commit to an agreement prior to receipt of additional

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clinical data, if at all. In the absence of such data, potential collaborative partners may demand economic terms that are unfavorable to us, or may be unwilling to collaborate with us at all. Even if Oncophage generates favorable clinical data over the next several years, we may not be able to negotiate a collaborative transaction at all, or negotiate one that provides us with favorable economic terms.

In addition, we would consider license and/or co-development opportunities to advance Aroplatin and AG-707. These products are at an early stage, and collaborative partners or licensees may defer discussions until results from early clinical trials become available, or they may not engage in such discussions at all. Further work on these programs is on hold due to cost-containment efforts.

***Because we rely on collaborators and licensees for the development and commercialization of some of our product candidate programs, these programs may not prove successful, and/or we may not receive significant payments from such parties.***

Part of our strategy is to develop and commercialize some of our product candidates by continuing our existing arrangements with academic and corporate collaborators and licensees and by entering into new collaborations. Our success depends on our ability to negotiate such agreements and on the success of the other parties in performing research, preclinical and clinical testing, completing regulatory applications, and commercializing product candidates. For example, the development of Oncophage for the treatment of glioma is currently dependent in large part on the efforts of our institutional collaborators, such as the Brain Tumor Research Center at the University of California, San Francisco, which is conducting Phase 2 clinical trials of Oncophage for the treatment of glioma. In addition, all product candidates containing QS-21 depend on the success of our collaborative partners or licensees, and the Company's relationships with these third parties. Such product candidates depend on the successful and adequate manufacture and/or supply of QS-21, and our collaborators and licensees successfully enrolling patients and completing clinical trials, being committed to dedicating the resources to advance these product candidates, obtaining regulatory approvals, and successfully commercializing product candidates.

These development activities may fail to produce marketable products due to unsuccessful results or abandonment of these programs, failure to enter into future collaborations or license agreements, or the inability to manufacture product supply requirements for our collaborators and licensees. For example, in August 2006, Pharmexa A/S announced a decision to cease dosing patients in their Phase 2 clinical trial of their HER-2 Protein AutoVac breast cancer vaccine containing our QS-21 adjuvant, after it was determined that the trial was unlikely to meet its primary endpoint. Several of our agreements also require us to transfer important rights and regulatory compliance responsibilities to our collaborators and licensees. As a result of collaborative agreements, we will not control the nature, timing, or cost of bringing these product candidates to market. Our collaborators and licensees could choose not to devote resources to these arrangements or, under certain circumstances, may terminate these arrangements early. They may cease pursuing product candidates or elect to collaborate with different companies. In addition, these collaborators and licensees, outside of their arrangements with us, may develop technologies or products that are competitive with those that we are developing. From time to time, we may also become involved in disputes with our collaborators or licensees. Such disputes could result in the incurrence of significant expense, or the termination of collaborations. We may be unable to fulfill all of our obligations to our collaborators, which may result in the termination of collaborations. As a result of these factors, our strategic collaborations may not yield revenue. Furthermore, we may be unable to enter into new collaborations or enter into new collaborations on favorable terms. Failure to generate significant revenue from collaborations would increase our need to fund our operations through sales of securities and would negatively affect our business prospects.

***If we are unable to purify heat shock proteins from some cancer types, we may have difficulty successfully initiating clinical trials in new indications or completing our clinical trials, and, even if we do successfully complete our clinical trials, the size of our potential market could decrease.***

Our ability to successfully develop and commercialize Oncophage for a particular cancer type depends in part on our ability to purify heat shock proteins from that type of cancer. If we experience difficulties in purifying heat shock proteins for a sufficiently large number of patients in our clinical trials, it may lower the probability of a successful analysis of the data from these trials and, ultimately, the ability to obtain regulatory approvals. For example, our inability to manufacture adequate amounts of Oncophage for approximately 30% of the patients randomized in the Oncophage treatment arm of the Phase 3 metastatic melanoma trial undermined the potential for the trial to meet its pre-specified clinical endpoints. To address this lower success rate for melanoma, we included additional protease inhibitors in the manufacturing process to further limit the breakdown of the product. Subsequent to the implementation of this change, we successfully produced Oncophage for 18 of 23 patients, a success rate of approximately 78%, whereas previously we had produced Oncophage for 123 of 179 patients, a success rate of approximately 69%. The small sample size used subsequent to our process change may make the reported improvement in our manufacturing success unreliable as a predictor of future success.

We have successfully manufactured product for 100%, 10 of 10, of the patients randomized to treatment in our Phase 2 lung cancer trial and 95%, 21 of 22, of the patients randomized to treatment in our Phase 2 metastatic renal cell carcinoma trial. Based on our clinical trials to date, we have been able to manufacture Oncophage from 87% of the tumors delivered to our manufacturing facilities in Massachusetts; for non-metastatic renal cell carcinoma, 92%; for melanoma, 70%; for colorectal cancer, 98%; for gastric cancer, 81%; for lymphoma, 89%; for



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glioma, 86%; and for pancreatic cancer, 46%. The relatively low rate of manufactured product for pancreatic cancer is due to the abundance of proteases in pancreatic tissue. Proteases, which are enzymes that break down proteins, are believed to degrade the heat shock proteins during the purification process.

We may encounter problems with other types of cancer as we expand our research. If we cannot overcome these problems, the number of cancer types that our heat shock protein product candidates could treat would be limited. In addition, if we commercialize our heat shock protein product candidates, we may not be able to replicate past manufacturing success rates and we may face claims from patients for whom we are unable to produce a vaccine.

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***If we fail to sustain and further build our intellectual property rights, competitors will be able to take advantage of our research and development efforts to develop competing products.***

If we are not able to protect our proprietary technology, trade secrets, and know-how, our competitors may use our inventions to develop competing products. We currently have exclusive rights to 76 issued United States patents and 101 foreign patents. We also have exclusive rights to 14 pending United States patent applications and 66 pending foreign patent applications. However, we currently do not have any issued patents in Russia covering Oncophage and we may not have rights to Oncophage patents in other territories where we may pursue regulatory approval. In addition, our patents may not protect us against our competitors. Our patent positions, and those of other pharmaceutical and biotechnology companies, are generally uncertain and involve complex legal, scientific, and factual questions. The standards which the United States Patent and Trademark Office uses to grant patents, and the standards which courts use to interpret patents, are not always applied predictably or uniformly and can change, particularly as new technologies develop. Consequently, the level of protection, if any, that will be provided by our patents if we attempt to enforce them, and they are challenged, is uncertain. In addition, the type and extent of patent claims that will be issued to us in the future is uncertain. Any patents that are issued may not contain claims that permit us to stop competitors from using similar technology.

In addition to our patented technology, we also rely on unpatented technology, trade secrets, and confidential information. We may not be able to effectively protect our rights to this technology or information. Other parties may independently develop substantially equivalent information and techniques or otherwise gain access to or disclose our technology. We generally require each of our employees, consultants, collaborators, and certain contractors to execute a confidentiality agreement at the commencement of an employment, consulting, collaborative, or contractual relationship with us. However, these agreements may not provide effective protection of our technology or information, or in the event of unauthorized use or disclosure, they may not provide adequate remedies.

***We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, and we may be unable to protect our rights to, or use, our technology.***

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. We may become a party to patent litigation or other proceedings regarding intellectual property rights.

If we choose to go to court to stop someone else from using the inventions claimed in our patents, that individual or company has the right to ask a court to rule that our patents are invalid and should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of our patents. In addition, there is a risk that the court will decide that our patents are not valid and that we do not have the right to stop the other party from using the claimed inventions. There is also the risk that, even if the validity of our patents is upheld, the court will refuse to stop the other party on the grounds that such other party's activities do not infringe our patents.

We may not have rights under some patents or patent applications related to some of our existing and proposed products or processes. Third parties may own or control these patents and patent applications in the United States and abroad. Therefore, in some cases, such as those described below, in order to develop, use, manufacture, sell, or import some of our existing or proposed products, or develop or use some of our existing or proposed processes, we or our collaborators may choose to seek, or be required to seek, licenses under third-party patents issued in the United States and abroad, or those that might issue from United States and foreign patent applications. In such an event, we likely would be required to pay license fees or royalties or both to the licensor. If licenses are not available to us on acceptable terms, we or our collaborators may not be able to exploit these products or processes.

Furthermore, a third party may claim that we are using inventions covered by such third-party's patents or other intellectual property rights and may go to court to stop us from engaging in our normal operations and activities. These lawsuits are expensive. Some of our competitors may be able to sustain the cost of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party substantial damages for having violated the other party's patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. Moreover, patent holders sometimes send communications to a number of companies in related fields suggesting possible infringement, and we, like a number of biotechnology companies, have received such communications, including communications alleging infringement of a patent relating to certain gel-fiberglass structures. If we are sued for patent infringement, we would need to demonstrate that our products either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, which we may not be able to do. Proving invalidity, in particular, is difficult, since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

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If patent litigation or other proceeding is resolved against us, we or our licensees or collaborators may be enjoined from using, manufacturing, selling, or importing our products or processes without a license from the other party, and we may be held liable for significant damages. We may not be able to obtain any required licenses on commercially acceptable terms or at all.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to enter into collaborations with other entities, obtain financing, or compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time and other resources.

*Our patent protection for any compound or product that we seek to develop may be limited to a particular method of use or indication such that, if a third party were to obtain approval of the compound or product for use in another indication, we could be subject to competition arising from off-label use.*

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The patent landscape in our business is becoming increasingly congested with competing applications for protection of closely related compounds and technologies that arise from both industrial and academic research. Although we generally seek the broadest patent protection available for our proprietary compounds, competing art may prevent us from obtaining patent protection for the actual composition of matter of any particular compound and we may be limited to protecting a new method of use for the compound or otherwise restricted in our ability to prevent others from exploiting the compound. If we are unable to obtain patent protection for the actual composition of matter of any compound that we seek to develop and commercialize and must rely on method of use patent coverage, we would likely be unable to prevent others from manufacturing or marketing that compound for any use that is not protected by our patent rights. If a third party were to receive marketing approval for the compound for another use, physicians might nevertheless prescribe it for indications that are not described in the product's labeling or approved by the FDA or other regulatory authorities. Even if we have patent protection of the prescribed indication, as a practical matter, we likely would have little recourse as a result of this off-label use. In that event, our revenues from the commercialization of the compound would likely be adversely affected.

***If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.***

We are a party to various license agreements under which we receive the right to practice and use important third-party patent rights and we may enter into additional licenses in the future. Our existing licenses impose, and we expect future licenses will impose, various diligence, milestone payment, royalty, insurance, and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we might not be able to market any product that is covered by the licensed patents.

***If we fail to retain the services of, and/or maintain positive relations with, key individuals and our employees, we may be unable to successfully develop our product candidates, conduct clinical trials, and obtain financing.***

Garo H. Armen, Ph.D., the Chairman of our Board of Directors and our Chief Executive Officer, co-founded Antigenics in 1994 with Pramod K. Srivastava, Ph.D., and has been and continues to be integral to building our company and developing our technology. If Dr. Armen severed his relationship with Antigenics, our business may be adversely impacted.

Effective December 1, 2005, we entered into an employment agreement with Dr. Armen. Subject to the earlier termination as provided in the agreement, the agreement had an original term of one year and is automatically extended thereafter for successive terms of one year each, unless either party provides notice to the other at least ninety days prior to the expiration of the original or any extension term. Dr. Armen plays an important role in our day-to-day activities. We do not carry key employee insurance policies for Dr. Armen or any other employee.

Dr. Srivastava currently has a consulting agreement with us pursuant to which he is retained to provide advice and services to Antigenics from time to time. This agreement has an initial term ending March 31, 2011.

We also rely greatly on employing and retaining other highly trained and experienced senior management and scientific and operations personnel. The competition for these and other qualified personnel in the biotechnology field is intense. In order to reduce our expenses, we have eliminated certain employee benefits, restructured our business, and reduced staffing levels. This restructuring has in many cases eliminated any redundancy in skills and capabilities in key areas. If we are not able to attract and retain qualified personnel, we may not be able to achieve our strategic and operational objectives.

***We may face litigation that could result in substantial damages and may divert management's time and attention from our business.***

Antigenics, our Chairman and Chief Executive Officer, Garo H. Armen, Ph.D., and two investment banking firms that served as underwriters in our initial public offering have been named as defendants in a federal civil class action lawsuit pending in the United States District Court for the Southern District of New York. Substantially similar actions were filed concerning the initial public offerings for more than 300 different issuers, and the cases were coordinated as *In re Initial Public Offering Securities Litigation*, 21 MC 92 for pre-trial purposes. The suit alleges that the brokerage arms of the investment banking firms charged secret excessive commissions to certain of their customers in return for allocations of our stock in the offering. The suit also alleges that shares of our stock were allocated to certain of the investment banking firms' customers based upon agreements by such customers to purchase additional shares of our stock in the secondary market. Dr. Armen has been dismissed without prejudice from the lawsuit pursuant to a stipulation. In June 2004, a stipulation of settlement and release of claims against the issuer defendants, including us, was submitted to the Court for approval. The Court preliminarily approved the settlement in August 2005. In December 2006, the appellate court overturned the certification of classes in six test cases that were selected by the underwriter defendants and plaintiffs in the coordinated proceedings. The case involving Antigenics is not one of the six test cases. Class certification had been one of the conditions of the settlement. Accordingly, on June 25, 2007, the Court entered an order terminating the proposed settlement based on a stipulation among the parties to the settlement. Plaintiffs have filed amended master allegations and amended complaints in the six test cases. On

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March 26, 2008, the Court largely denied the defendants' motion to dismiss the amended complaints. The parties have reached a global settlement of the litigation. On October 5, 2009, the Court entered an order granting final approval of the settlement. Under the settlement, the insurers will pay the full amount of settlement share allocated to the defendants, and the defendants will bear no financial liability. The company defendants, as well as the officer and director defendants who were previously dismissed from the action pursuant to tolling agreements, will receive complete dismissals from the case. A group of objectors has filed a petition requesting permission to appeal the Court's October 5, 2009 order certifying the settlement class. If for any reason the settlement does not become effective, we believe we have meritorious defenses to the claims and intend to defend the action vigorously. We are unable to predict the likelihood of an unfavorable outcome or estimate our potential liability, if any.

In addition, we are involved in other litigation and may become involved in additional litigation. Any such litigation could be

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expensive in terms of out-of-pocket costs and management time, and the outcome of any such litigation is uncertain.

Our directors and officers insurance policies provide \$25.0 million annual aggregate coverage and \$25.0 million per occurrence coverage. This limited insurance coverage may not be sufficient to cover us for future claims.

### ***Product liability and other claims against us may reduce demand for our products and/or result in substantial damages.***

We face an inherent risk of product liability exposure related to testing our product candidates in human clinical trials and will face even greater risks upon the sale of Oncophage commercially, as well as if we sell our other product candidates commercially. An individual may bring a product liability claim against us if Oncophage or one of our product candidates causes, or merely appears to have caused, an injury. Product liability claims may result in:

decreased demand for Oncophage or our product candidates;

regulatory investigations;

injury to our reputation;

withdrawal of clinical trial volunteers;

costs of related litigation; and

substantial monetary awards to plaintiffs.

We manufacture Oncophage from a patient's cancer cells, and a medical professional must inject Oncophage into the same patient from which it was manufactured. A patient may sue us if a hospital, a shipping company, or we fail to deliver the removed cancer tissue or that patient's Oncophage. We anticipate that the logistics of shipping will become more complex if the number of patients we treat increases and that shipments of tumor and/or Oncophage may be lost, delayed, or damaged. Additionally, complexities unique to the logistics of commercial products may delay shipments and limit our ability to move commercial product in an efficient manner without incident. Currently, we do not have insurance that covers loss of or damage to Oncophage or tumor material, and we do not know whether such insurance will be available to us at a reasonable price or at all. We have limited product liability coverage for use of our product candidates. Our product liability policy provides \$10.0 million aggregate coverage and \$10.0 million per occurrence coverage. This limited insurance coverage may be insufficient to fully cover us for future claims.

### ***If we do not comply with environmental laws and regulations, we may incur significant costs and potential disruption to our business.***

We use hazardous, infectious, and radioactive materials, and recombinant DNA in our operations, which have the potential of being harmful to human health and safety or the environment. We store these hazardous (flammable, corrosive, toxic), infectious, and radioactive materials, and various wastes resulting from their use, at our facilities pending use and ultimate disposal. We are subject to a variety of federal, state, and local laws and regulations governing use, generation, storage, handling, and disposal of these materials. We may incur significant costs complying with both current and future environmental health and safety laws and regulations. In particular, we are subject to regulation by the Occupational Safety and Health Administration, the Environmental Protection Agency, the Drug Enforcement Agency, the Department of Transportation, the Centers for Disease Control and Prevention, the National Institutes of Health, the International Air Transportation Association, and various state and local agencies. At any time, one or more of the aforementioned agencies could adopt regulations that may affect our operations. We are also subject to regulation under the Toxic Substances Control Act and the Resource Conservation Development programs.

Although we believe that our current procedures and programs for handling, storage, and disposal of these materials comply with federal, state, and local laws and regulations, we cannot eliminate the risk of accidents involving contamination from these materials. Although we have

limited pollution liability coverage (\$2.0 million) and a workers' compensation liability policy, we could be held liable for resulting damages in the event of an accident or accidental release, and such damages could be substantially in excess of any available insurance coverage and could substantially disrupt our business.

### **Risks Related to our Common Stock**

#### ***Our officers and directors may be able to block proposals for a change in control.***

Antigenics Holdings LLC is a holding company that owns shares of our common stock, and as of September 30, 2009, Antigenics Holdings LLC controlled approximately 12% of our outstanding common stock. Due to this concentration of ownership, Antigenics Holdings LLC can substantially influence all matters requiring a stockholder vote, including:

the election of directors;

the amendment of our organizational documents; or

the approval of a merger, sale of assets, or other major corporate transaction.

Our Chief Executive Officer directly and indirectly owns approximately 48% of Antigenics Holdings LLC. In addition, several of our directors and officers directly and indirectly own approximately 4% of our outstanding common stock.

***The unaffiliated holders of certain convertible securities have the right to convert such securities into a substantial percentage of our outstanding common stock.***

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According to publicly filed documents, Mr. Brad M. Kelley beneficially owns 5,546,240 shares of our outstanding common stock and 31,620 shares of our series A convertible preferred stock. The shares of preferred stock are currently convertible at any time into 2,000,000 shares of common stock at an initial conversion price of \$15.81, are non-voting, and carry a 2.5% annual dividend yield. If Mr. Kelley had converted all of the shares of preferred stock on September 30, 2009, he would have held approximately 8% of our outstanding common stock. We currently have a right of first refusal agreement with Mr. Kelley that provides us with limited rights to purchase certain of Mr. Kelley's shares if he proposes to sell them to a third party.

Mr. Kelley's substantial ownership position provides him with the ability to substantially influence the outcome of matters submitted to our stockholders for approval. Furthermore, collectively, Mr. Kelley and Antigenics Holdings LLC control approximately 19% of our outstanding common stock as of September 30, 2009, providing substantial ability, if they vote in the same manner, to determine the outcome of matters submitted to a stockholder vote. If Mr. Kelley were to convert all of his preferred stock into common stock, the combined total would increase to 20%. Additional purchases of our common stock by Mr. Kelley also would increase both his percentage of outstanding voting rights and the percentage combined with Antigenics Holdings LLC. While Mr. Kelley's shares of preferred stock do not carry voting rights, the shares of common stock issuable upon conversion carry the same voting rights as other shares of common stock.

On October 30, 2006, we issued \$25.0 million of our 2006 Notes to a group of institutional investors. These 2006 Notes, together with any interest paid in the form of additional 2006 Notes, are convertible into our common stock at a conversion price of \$3.00 per share at the option of the investors. On September 30, 2009, one holder of the 2006 Notes had holdings which, if totally converted into shares of our common stock, would result in this holder owning 7,045,000 shares. If such holder had exercised such conversion right on September 30, 2009, such holder would have owned approximately 7% of our outstanding common stock.

While the 2006 Notes do not carry any voting rights, the common stock issuable upon conversion of such securities do carry the same voting rights as other shares of common stock. The ownership positions following any such conversion, along with any open market purchases by such holders, could provide the holders with the ability to substantially influence the outcome of matters submitted to our stockholders for approval.

### ***Provisions in our organizational documents could prevent or frustrate attempts by stockholders to replace our current management.***

Our certificate of incorporation and bylaws contain provisions that could make it more difficult for a third party to acquire us without the consent of our Board of Directors. Our certificate of incorporation provides for a staggered board and removal of directors only for cause. Accordingly, stockholders may elect only a minority of our Board at any annual meeting, which may have the effect of delaying or preventing changes in management. In addition, under our certificate of incorporation, our Board of Directors may issue additional shares of preferred stock and determine the terms of those shares of stock without any further action by our stockholders. Our issuance of additional preferred stock could make it more difficult for a third party to acquire a majority of our outstanding voting stock and thereby effect a change in the composition of our Board of Directors. Our certificate of incorporation also provides that our stockholders may not take action by written consent. Our bylaws require advance notice of stockholder proposals and director nominations and permit only our President or a majority of the Board of Directors to call a special stockholder meeting. These provisions may have the effect of preventing or hindering attempts by our stockholders to replace our current management. In addition, Delaware law prohibits a corporation from engaging in a business combination with any holder of 15% or more of its capital stock until the holder has held the stock for three years unless, among other possibilities, the Board of Directors approves the transaction. Our Board of Directors may use this provision to prevent changes in our management. Also, under applicable Delaware law, our Board of Directors may adopt additional anti-takeover measures in the future.

### ***Our stock has generally had low trading volume, and its public trading price has been volatile.***

Between our initial public offering on February 4, 2000 and September 30, 2009, and for the nine months ended September 30, 2009, the closing price of our common stock has fluctuated between \$0.30 and \$52.63 per share and \$0.30 and \$2.99 per share, respectively. The average daily trading volume for the nine months ended September 30, 2009 was approximately 2,131,000 shares, which is a significant increase from our average trading volume for the three months ended March 31, 2009 of 111,000 shares. The market may experience significant price and volume fluctuations that are often unrelated to the operating performance of individual companies. In addition to general market volatility, many factors may have a significant adverse effect on the market price of our stock, including:

continuing operating losses, which we expect over the next several years as we continue our development activities;

announcements of decisions made by public officials;



results of our preclinical studies and clinical trials;

announcements of technological innovations, new commercial products, failures of products, or progress toward commercialization by our competitors or peers;

developments concerning proprietary rights, including patent and litigation matters;

publicity regarding actual or potential results with respect to product candidates under development by us or by our competitors;

regulatory developments; and

quarterly fluctuations in our financial results.

***The sale of a significant number of shares could cause the market price of our stock to decline.***

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The sale by us or the resale by stockholders of a significant number of shares of our common stock could cause the market price of our common stock to decline. As of September 30, 2009, we had 89,714,639 shares of common stock outstanding. All of these shares are eligible for sale on the NASDAQ, although certain of the shares are subject to sales volume and other limitations. We have filed registration statements to permit the sale of 25,436,831 shares of common stock under our equity incentive plan and certain equity plans that we assumed in the acquisitions of Aquila Biopharmaceuticals, Inc. and Aronex Pharmaceuticals, Inc. We have also filed registration statements to permit the sale of 1,000,000 shares of common stock under our employee stock purchase plan, to permit the sale of 450,000 shares of common stock under our Directors Deferred Compensation Plan, to permit the sale of 17,417,434 shares of common stock pursuant to the private placement agreement dated January 9, 2008, to permit the sale of 14,000,000 shares of common stock pursuant to the private placement agreement dated April 8, 2008 and to permit the sale of 9,673,900 shares of common stock pursuant to a private placement agreement dated August 3, 2009. As of September 30, 2009, an aggregate of 36,809,200 shares remain available for sale under these registration statements. The market price of our common stock may decrease based on the expectation of such sales.

As of September 30, 2009, options to purchase 6,430,105 shares of our common stock with a weighted average exercise price per share of \$2.89 were outstanding. Many of these options are subject to vesting that generally occurs over a period of up to four years following the date of grant. As of September 30, 2009, we have 216,938 nonvested shares outstanding.

***If we fail to meet the requirements for continued listing on the NASDAQ Capital Market, our common stock could be delisted from trading, which would adversely affect the liquidity of our common stock and our ability to raise additional capital.***

Our common stock is currently listed for quotation on the NASDAQ Capital Market. Accordingly, we are required to meet specified financial requirements in order to maintain our listing. One such requirement is that we maintain a minimum closing bid price of at least \$1.00 per share for our common stock. Our common stock has recently closed at prices that are below this minimum bid price requirement. If our stock price falls below \$1.00 per share for 30 consecutive business days, we could receive a deficiency notice from NASDAQ advising us that we have 180 days to regain compliance. Thereafter, we could receive an additional 180-day compliance period if we meet all initial inclusion requirements for the NASDAQ Capital Market, except for the bid price requirement. In order to achieve compliance with the bid price requirement, a security must maintain a closing \$1.00 bid price for a minimum of 10 consecutive business days. If a company does not demonstrate compliance within the compliance period, it will be issued a delisting letter, which it may appeal at that time. If in the future we fail to satisfy the NASDAQ's continued listing requirements, our common stock could be delisted from the NASDAQ Capital Market. Any potential delisting of our common stock from the NASDAQ Capital Market would make it more difficult for our stockholders to sell our stock in the public market and would likely result in decreased liquidity and increased volatility for our common stock.

***Because we are a relatively small public company we believe we have been disproportionately negatively impacted by the Sarbanes-Oxley Act of 2002 and related regulations which have increased our costs in the past and have required additional management resources.***

The Sarbanes-Oxley Act of 2002 and rules adopted by the SEC and the NASDAQ have resulted in significant costs to us. In particular, our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and related regulations regarding the required assessment of our internal control over financial reporting, and our independent registered public accounting firm's audit of internal control over financial reporting, have required commitments of significant management time. We expect these commitments to continue. Additionally, these laws and regulations could make it more difficult for us to attract and retain qualified members for our Board of Directors, particularly independent directors, or qualified executive officers.

Our internal control over financial reporting (as defined in Rules 13a-15 of the Securities Exchange Act) is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements for external purposes in accordance with U.S. GAAP. Because of its inherent limitations, internal control over financial reporting may not prevent or detect all deficiencies or weaknesses in our financial reporting. While our management has concluded that there were no material weaknesses in our internal control over financial reporting as of December 31, 2008, our procedures are subject to the risk that our controls may become inadequate because of changes in conditions or as a result of a deterioration in compliance with such procedures. No assurance is given that our procedures and processes for detecting weaknesses in our internal control over financial reporting will be effective.

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**Item 6.      *Exhibits***

The exhibits listed in the Exhibit Index are included in this Quarterly Report on Form 10-Q.

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**ANTIGENICS INC.**

**SIGNATURES**

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

Date: November 9, 2009

ANTIGENICS INC.

/s/ SHALINI SHARP

**Shalini Sharp**

*Chief Financial Officer*

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**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
3.1	Amended and Restated Certificate of Incorporation of Antigenics Inc. filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) dated June 10, 2002 and incorporated herein by reference.
3.1.1	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Antigenics Inc. filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) dated June 11, 2007 and incorporated herein by reference.
3.2	Third Amended and Restated By-laws of Antigenics Inc. filed as Exhibit 3.2 to our Quarterly Report on Form 10-Q/A (File No. 0-29089) dated November 10, 2008 and incorporated herein by reference.
3.3	Certificate of Designation, Preferences and Rights of the Series A Convertible Preferred Stock of Antigenics Inc. filed with the Secretary of State of the State of Delaware on September 24, 2003. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on September 25, 2003 and incorporated herein by reference.
3.4	Certificate of Designations, Preferences and Rights of the Class B Convertible Preferred Stock of Antigenics Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on September 5, 2007 and incorporated herein by reference.
4.1	Form of 6 Month Warrant under the Securities Purchase Agreement dated July 30, 2009. Filed as Exhibit 4.1 to our Current Report on Form 8-K (File No. 0-29089) filed on August 3, 2009 and incorporated herein by reference.
4.2	Form of 4 Year Warrant under the Securities Purchase Agreement dated July 30, 2009. Filed as Exhibit 4.2 to our Current Report on Form 8-K (File No. 0-29089) filed on August 3, 2009 and incorporated herein by reference.
4.3	Waiver of Rights Upon Issuance of Other Securities dated July 29, 2009 between Antigenics Inc. and Ingalls & Snyder Value Partners L.P. Filed herewith.
4.4	Form of 6 Month Warrant under the Securities Purchase Agreement dated August 3, 2009. Filed as Exhibit 4.1 to our Current Report on Form 8-K (File No. 0-29089) filed on August 5, 2009 and incorporated herein by reference.
4.5	Form of 4 Year Warrant under the Securities Purchase Agreement dated August 3, 2009. Filed as Exhibit 4.2 to our Current Report on Form 8-K (File No. 0-29089) filed on August 5, 2009 and incorporated herein by reference.
4.6	Waiver of Rights Upon Issuance of Other Securities dated August 3, 2009 between Antigenics Inc. and Ingalls & Snyder Value Partners L.P. Filed herewith.
10.1*	First Amendment to Employment Agreement dated July 2, 2009 between Antigenics Inc. and Garo Armen. Filed herewith.
10.2*	First Amendment to Employment Agreement dated July 2, 2009 between Antigenics Inc. and Shalini Sharp. Filed herewith.
10.3*	First Amendment to Employment Agreement dated July 2, 2009 between Antigenics Inc. and Karen Valentine. Filed herewith.
10.4*	First Amendment to Employment Agreement dated July 2, 2009 between Antigenics Inc. and Kerry Wentworth. Filed herewith.
10.5(1)	Amended and Restated License Agreement by and between Antigenics Inc., a Massachusetts corporation and wholly owned subsidiary of Antigenics Inc., Elan Pharma International Limited, and Elan Pharmaceuticals, Inc. dated September 14, 2009. Filed herewith.
10.6	Notice of Assignment of Amended and Restated License Agreement by and between Antigenics Inc., a Massachusetts corporation and wholly owned subsidiary of Antigenics Inc., Elan Pharma International Limited, and Elan Pharmaceuticals, Inc. dated September 17, 2009. Filed herewith.
10.7(1)	Supply Agreement by and between Antigenics Inc. and ISSI-Strategy LLC dated July 9, 2009. Filed herewith.
10.8	Securities Purchase Agreement dated as of July 30, 2009 by and among Antigenics Inc. and the investors listed on the Schedule of Buyers thereto. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on August 3, 2009 and incorporated herein by reference.
10.9	

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Securities Purchase Agreement dated as of August 3, 2009 by and among Antigenics Inc. and the investors listed on the Schedule of Buyers thereto. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 0-29089) filed on August 5, 2009 and incorporated herein by reference.

- 31.1 Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended. Filed herewith.
- 31.2 Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended. Filed herewith.
- 32.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Furnished herewith.

\* Indicates a management contract or compensatory plan.

- (1) Certain confidential material contained in the document has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended or Rule 24b-2 of the Securities Exchange Act of 1934, as amended.