

AGENUS INC
Form 10-Q
August 05, 2011
[Table of Contents](#)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-Q

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

For the Quarterly Period Ended June 30, 2011

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

For the transition period from _____ to _____

Commission File No. 000-29089

Agenus Inc.

(Exact Name of Registrant as Specified in its Charter)

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Delaware
(State of Incorporation)

06-1562417
(I.R.S. Employer
Identification Number)

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, or a non-accelerated filer. See definition of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.:

Large accelerated filer Accelerated filer

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

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

Number of shares outstanding of the issuer's Common Stock as of August 2, 2011: 114,197,583 shares.

Table of Contents

Agenus Inc.

Quarterly Period Ended June 30, 2011

Table of Contents

| | Page |
|---|-------------|
| PART I FINANCIAL INFORMATION | |
| Item 1. | |
| Financial Statements: | |
| <u>Condensed Consolidated Balance Sheets as of June 30, 2011 and December 31, 2010 (Unaudited)</u> | 2 |
| <u>Condensed Consolidated Statements of Operations for the quarters and six months ended June 30, 2011 and 2010 (Unaudited)</u> | 3 |
| <u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2011 and 2010 (Unaudited)</u> | 4 |
| <u>Notes to Unaudited Condensed Consolidated Financial Statements</u> | 5 |
| Item 2. | |
| <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> | 12 |
| Item 3. | |
| <u>Quantitative and Qualitative Disclosures About Market Risk</u> | 19 |
| Item 4. | |
| <u>Controls and Procedures</u> | 19 |
| PART II OTHER INFORMATION | |
| Item 1. | |
| <u>Legal Proceedings</u> | 21 |
| Item 1A. | |
| <u>Risk Factors</u> | 21 |
| Item 6. | |
| <u>Exhibits</u> | 35 |
| <u>Signatures</u> | 36 |

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

| | June 30, 2011 | December 31, 2010 |
|--|----------------------|----------------------|
| ASSETS | | |
| Cash and cash equivalents | \$ 12,016,136 | \$ 19,781,976 |
| Accounts receivable | 188 | 35,000 |
| Inventories | 26,432 | 26,432 |
| Prepaid expenses | 830,653 | 704,744 |
| Other current assets | 422,196 | 306,008 |
| Total current assets | 13,295,605 | 20,854,160 |
| Plant and equipment, net of accumulated amortization and depreciation of \$25,639,004 and \$24,993,225 at June 30, 2011 and December 31, 2010, respectively | 5,095,063 | 6,194,465 |
| Goodwill | 2,572,203 | 2,572,203 |
| Other long-term assets | 1,268,254 | 1,285,831 |
| Total assets | \$ 22,231,125 | \$ 30,906,659 |
| LIABILITIES AND STOCKHOLDERS DEFICIT | | |
| Current portion, long-term debt | \$ 146,061 | \$ 146,061 |
| Current portion, deferred revenue | 1,539,756 | 1,540,385 |
| Accounts payable | 340,034 | 698,554 |
| Accrued liabilities | 2,244,067 | 2,684,609 |
| Other current liabilities | 536,853 | 346,314 |
| Total current liabilities | 4,806,771 | 5,415,923 |
| Convertible senior notes | 30,458,075 | 34,050,033 |
| Deferred revenue | 2,842,593 | 3,612,156 |
| Derivative liability (Note G) | | 755,000 |
| Other long-term liabilities | 1,275,979 | 1,780,759 |
| 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 June 30, 2011 and December 31, 2010; liquidation value of \$31,817,625 at June 30, 2011 | 316 | 316 |
| Series B2 convertible preferred stock; 3,105 shares designated, issued, and outstanding at June 30, 2011 and December 31, 2010 | 31 | 31 |
| Common stock, par value \$0.01 per share; 250,000,000 shares authorized; 114,326,623 and 111,885,759 shares issued at June 30, 2011 and December 31, 2010, respectively | 1,143,266 | 1,118,858 |
| Additional paid-in capital | 578,168,656 | 568,916,796 |
| Treasury stock, at cost; 260,944 shares of common stock at June 30, 2011 and December 31, 2010 | (324,792) | (324,792) |
| Accumulated deficit | (596,139,770) | (584,418,421) |
| Total stockholders' deficit | (17,152,293) | (14,707,212) |

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| | | |
|---|---------------|---------------|
| Total liabilities and stockholders' deficit | \$ 22,231,125 | \$ 30,906,659 |
|---|---------------|---------------|

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

AGENUS INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

| | Quarters Ended June 30, | | Six Months Ended June 30, | |
|--|----------------------------|-----------------------|------------------------------|------------------------|
| | 2011 | 2010 | 2011 | 2010 |
| Revenue: | | | | |
| Product revenue | \$ | \$ 35,000 | \$ | \$ 35,000 |
| Research and development revenue | 786,432 | 770,171 | 1,458,313 | 1,706,599 |
| Total revenues | 786,432 | 805,171 | 1,458,313 | 1,741,599 |
| Operating expenses: | | | | |
| Cost of goods sold | | 57,898 | | 57,898 |
| Research and development | 2,823,626 | 2,628,896 | 5,639,002 | 7,260,180 |
| General and administrative | 2,664,322 | 2,767,354 | 5,543,262 | 6,333,451 |
| Operating loss | (4,701,516) | (4,648,977) | (9,723,951) | (11,909,930) |
| Other income (expense): | | | | |
| Non-operating income (expense) | (7,684) | 880,992 | (816) | 563,134 |
| Interest expense | (1,052,851) | (1,214,412) | (2,008,368) | (2,454,739) |
| Interest income | 4,466 | 10,635 | 11,786 | 18,733 |
| Net loss | (5,757,585) | (4,971,762) | (11,721,349) | (13,782,802) |
| Dividends on series A convertible preferred stock | (197,625) | (197,625) | (395,250) | (395,250) |
| Net loss attributable to common stockholders | \$ (5,955,210) | \$ (5,169,387) | \$ (12,116,599) | \$ (14,178,052) |
| Per common share data, basic and diluted: | | | | |
| Net loss attributable to common stockholders | \$ (0.05) | \$ (0.05) | \$ (0.11) | \$ (0.15) |
| Weighted average number of common shares outstanding, basic and diluted | 114,024,389 | 95,754,625 | 113,449,856 | 93,381,452 |

See accompanying notes to unaudited condensed consolidated financial statements.

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

| | Six Months Ended June 30, | |
|--|--------------------------------------|----------------------|
| | 2011 | 2010 |
| Cash flows from operating activities: | | |
| Net loss | \$ (11,721,349) | \$ (13,782,802) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 1,133,682 | 1,881,200 |
| Intangible asset impairment | | 629,382 |
| Change in fair value of derivative liability | | 511,680 |
| Share-based compensation | 1,204,575 | 2,052,778 |
| Non-cash interest expense | 1,988,166 | 1,913,235 |
| Net gain on extinguishment of debt | | (1,063,746) |
| Loss on sale of property and equipment | 15,190 | 24,378 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 34,812 | (17,500) |
| Inventories | | 233,204 |
| Prepaid expenses | (125,909) | (108,354) |
| Accounts payable | (358,520) | (560,018) |
| Deferred revenue | (770,192) | (305,700) |
| Accrued liabilities and other current liabilities | 208,655 | (279,674) |
| Other operating assets and liabilities | (279,624) | (298,885) |
| Net cash used in operating activities | (8,670,514) | (9,170,822) |
| Cash flows from investing activities: | | |
| Proceeds from maturities of available-for-sale securities | 5,000,000 | 20,000,000 |
| Proceeds from sale of property and equipment | 17,974 | 35,800 |
| Purchases of available-for-sale securities | (4,998,799) | (19,993,238) |
| Purchases of plant and equipment | (49,867) | (69,217) |
| Net cash used in investing activities | (30,692) | (26,655) |
| Cash flows from financing activities: | | |
| Net proceeds from sales of equity | 1,288,024 | 8,244,029 |
| Proceeds from employee stock purchases | 42,592 | 27,938 |
| Payment of series A convertible preferred stock dividends | (395,250) | (395,250) |
| Net cash provided by financing activities | 935,366 | 7,876,717 |
| Net decrease in cash and cash equivalents | (7,765,840) | (1,320,760) |
| Cash and cash equivalents, beginning of period | 19,781,976 | 20,066,817 |
| Cash and cash equivalents, end of period | \$ 12,016,136 | \$ 18,746,057 |
| Non-cash financing activity: | | |
| Convertible Note adjustment to equity for conversion option | \$ 5,580,124 | |
| Reclassification of derivative liability into equity | \$ 755,000 | |
| Issuance of senior secured convertible notes as payment in-kind for interest | \$ 1,386,817 | \$ 1,282,190 |

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Issuance of common stock, \$0.01 par value, as payment of long-term debt including accrued and unpaid interest

\$ 1,125,918

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents**AGENUS INC. AND SUBSIDIARIES****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****June 30, 2011****Note A Business, Liquidity and Basis of Presentation**

Agenus Inc., formerly Antigenics Inc., (including its subsidiaries, also referred to as Agenus, 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 core technology portfolio consists of our Heat Shock Protein (HSP) Platform (based on our HSP based technologies) and our Saponin Platform (based on our saponin adjuvant based technologies). From our HSP Platform we are developing our Prophage Series of cancer vaccines. We have tested product candidates from our Prophage Series in Phase 3 clinical trials for both the treatment of renal cell carcinoma (RCC), the most common type of kidney cancer, and for metastatic melanoma, as well as in Phase 1 and Phase 2 clinical trials in a range of indications. Prophage Series vaccine R-100 is registered for use in Russia in RCC as Oncophage® vaccine (vitespen). Product candidates from our Prophage G-Series are currently in Phase 2 clinical trials in glioma, a type of brain cancer. Within our HSP Platform we are also developing recombinant HSP based technologies (the Recombinant Series). HerpV, a therapeutic vaccine candidate from the Recombinant Series has been tested in a Phase 1 clinical trial for the treatment of genital herpes. Within our Saponin Platform is QS-21 Stimulon® adjuvant, or QS-21, which is used by our licensees in numerous vaccines under development in trials, some as advanced as Phase 3, for a variety of diseases, including human immunodeficiency virus, cancer, Alzheimer's disease, malaria, shingles, human immunodeficiency virus, and tuberculosis. Our business activities have included product research and development, intellectual property prosecution, manufacturing, 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 June 30, 2011, we had an accumulated deficit of \$596.1 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 as of June 30, 2011, and the estimated proceeds from our license, supply, and collaborative agreements will be sufficient to satisfy our liquidity requirements into 2012. 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 feasible.

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 candidates are in various stages of development and 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 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 development of our Prophage Series vaccines is subject to further evaluation and uncertainty, and because HerpV is in early-stage clinical development, we are unable to reliably estimate the cost of completing research and development programs, the timing of bringing such programs to various markets, and, therefore, are unable to determine when, if ever, material cash inflows from operating activities are likely to commence. We will continue to adjust other spending as needed in order to preserve liquidity.

As of June 30, 2011, we had debt outstanding of \$36.3 million in principal, including \$36.1 million in principal of our 8% senior secured convertible notes due August 2014 (the 2006 Notes). We expect to attempt to raise additional funds in advance of depleting our current funds to repay existing obligations and for working capital purposes. We may attempt to raise additional funds by: (1) out-licensing technologies or products to one or more third parties, (2) renegotiating third party agreements, (3) selling assets, (4) securing additional debt financing and/or (5) selling equity securities. Satisfying long-term liquidity needs may require the successful commercialization and/or one or more partnering arrangements for (1) our product, Oncophage and/or our Prophage Series of cancer vaccines, (2) vaccines containing QS-21 under development by our licensees and/or (3) potentially other product candidates, each of which will require additional capital. 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.

Table of Contents

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. Operating results for the six months ended June 30, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011. 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, 2010 filed with the Securities and Exchange Commission.

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 income and 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 income per common share is calculated by dividing net income 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 instruments such as warrants, stock options, nonvested shares, convertible preferred stock, and convertible notes. Because we reported a net loss attributable to common stockholders for all periods presented, 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 the net loss per common share. Therefore, the following potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding as of June 30, 2011 and 2010, as they would be anti-dilutive:

| | At June 30, | |
|-----------------------------|-------------|------------|
| | 2011 | 2010 |
| Warrants | 19,856,302 | 22,049,284 |
| Stock options | 8,602,538 | 7,237,071 |
| Nonvested shares | 972,658 | 662,828 |
| Convertible preferred stock | 2,000,000 | 2,000,000 |

Note C 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 three or 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 are exercised or expire, by changes in the fair value of our common stock. A summary of option activity for the six months ended June 30, 2011 is presented below:

| | Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (in years) | Aggregate Intrinsic Value |
|----------------------------------|-----------|--|---|---------------------------------|
| Outstanding at December 31, 2010 | 7,272,850 | \$ 2.24 | | |
| Granted | 2,047,173 | 1.02 | | |
| Forfeited | (253,011) | 1.59 | | |

Table of Contents

| | Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (in years) | Aggregate Intrinsic Value |
|---|-----------|--|---|---------------------------------|
| Expired | (462,557) | 8.15 | | |
| Exercised | (1,917) | 0.75 | | |
| Outstanding at June 30, 2011 | 8,602,538 | \$ 1.65 | 7.6 | \$ 59,648 |
| Vested or expected to vest at June 30, 2011 | 8,236,154 | \$ 1.68 | 7.5 | \$ 55,503 |
| Exercisable at June 30, 2011 | 5,018,121 | \$ 2.02 | 6.8 | \$ 33,074 |

The weighted average grant-date fair values of options granted during the six months ended June 30, 2011, and 2010, were \$0.77, and \$0.61, respectively.

During the first six months of 2011, all options were granted with exercise prices equal to the fair market value of the underlying shares of common stock on the grant date. As of June 30, 2011, approximately \$1.7 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 2.2 years.

As of June 30, 2011, 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 approximately \$126,000. 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 grant.

A summary of nonvested stock activity for the six months ended June 30, 2011 is presented below:

| | Nonvested Shares | Weighted Average Grant Date Fair Value |
|----------------------------------|---------------------|---|
| Outstanding at December 31, 2010 | 513,449 | \$ 0.77 |
| Granted | 1,347,882 | 0.56 |
| Vested | (839,538) | 0.83 |
| Forfeited | (49,135) | 0.56 |
| Outstanding at June 30, 2011 | 972,658 | \$ 0.47 |

As of June 30, 2011, there was approximately \$382,000 of unrecognized share-based compensation expense related to these nonvested shares. This cost is expected to be recognized over a weighted average period of 1.5 years. The total intrinsic value of shares vested during the six months ended June 30, 2011 was \$793,429.

We issue new shares upon option exercises, purchases under the 2009 Employee Stock Purchase Plan (the "2009 ESPP"), vesting of nonvested stock, under the Directors' Deferred Compensation Plan and in lieu of 34% of the base salary of our Chief Executive Officer ("CEO"). During the six months ended June 30, 2011, 65,075 shares were issued under the

Table of Contents

2009 ESPP, and 842,926 shares were issued as a result of the vesting of nonvested stock. In addition, during the six months ended June 30, 2011, 81,525 shares were issued to our CEO in lieu of cash salary.

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

| | Quarter Ended | | Six Months Ended | |
|---|---------------|---------------|------------------|-----------------|
| | June 30, | | June 30, | |
| | 2011 | 2010 | 2011 | 2010 |
| Research and development | \$ 81 | \$ 153 | \$ 269 | \$ 740 |
| General and administrative | 482 | 340 | 936 | 1,313 |
| Total share-based compensation expense | \$ 563 | \$ 493 | \$ 1,205 | \$ 2,053 |

Note D Convertible Debt

On February 23, 2011, we entered into a Ninth Amendment of Rights Agreement (the Amendment) to the 2006 Notes. The Amendment extended the maturity date of the 2006 Notes to August 31, 2014, and waived the rights of the note holders to convert the 2006 Notes into our common stock. The Amendment also removed substantially all restrictions on us incurring indebtedness subordinate to the 2006 Notes and substantially all restrictions to issue our common stock. We also agreed to waive our right to prepay these notes in the event that our shares trade at a weighted average price over \$7.00 for a 30-day period.

Our 2006 Notes are secured by the equity of our wholly-owned subsidiary that holds the rights or patents to QS-21 and HerpV. At the option of the holders, our 2006 Notes can be converted in whole or in part into an equity interest in this subsidiary, subject to our ability to preempt the conversion by redeeming the 2006 Notes to be so converted at a price equal to the conversion amount of such notes plus an amount that, when taken together with any cash interest payments previously made with respect to such 2006 Notes, would generate a 30% annual internal rate of return to the holders. If converted into an equity interest of this subsidiary, the ownership interest in the subsidiary will be determined by multiplying (x) the quotient of the conversion amount divided by \$25.0 million, by (y) 30%. In addition, our 2006 Notes grant holders a right of first refusal in any future equity issuance in this subsidiary so that holders of our 2006 Notes may purchase up to 50% of any newly issued equity in this subsidiary. If the holders elect not to convert into the subsidiary, then at the maturity of the 2006 Notes, we may elect to repay the then outstanding balance in cash or in common stock, subject to certain limitations. If we elect to repay the notes in common stock, we are limited to the number of shares we can issue, whereby the note holders cannot beneficially own in excess of 9.99% of our outstanding common stock at any given time. At June 30, 2011, the outstanding principal balance of the 2006 Notes was \$36.1 million.

Prior to the Amendment, based on the guidance in Accounting Standards Codification (ASC) 815, *Derivatives and Hedging - Contracts in Entity's Own Equity*, the conversion feature embedded in the 2006 Notes was 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. As amended, the 2006 Notes no longer fall within this guidance since they are no longer convertible into our common stock, therefore, the conversion option is no longer valued as a derivative liability. Accordingly, the value of the derivative has been reduced to zero with a corresponding increase to additional-paid-in capital of \$755,000. Also, as the Amendment did not modify our ability to settle the 2006 Notes in cash, the 2006 Notes are now within the guidance of ASC 470-20, *Debt - Debt with Conversion and Other Options*. In accordance with this guidance, the debt and equity components of the 2006 Notes are bifurcated and accounted for separately based on the value and related interest rate of a non-convertible debt security with the same terms. The fair value of the 2006 Notes at February 23, 2011 (the date of the Amendment) was determined to be \$28.5 million. The equity (conversion option) component of the note has been included in additional paid-in capital on our condensed consolidated balance sheet and, accordingly, the carrying value of the 2006 Note was reduced by approximately \$5.6 million.

Note E Commitments and Contingencies

Agenus, our Chairman and CEO, Garo H. Armen, Ph.D., and two investment banking firms that served as underwriters in our initial public offering were named as defendants in a federal civil class action lawsuit 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 for pre-trial purposes as *In re Initial Public Offering Securities Litigation*, 21 MC 92. 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

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agreements by such customers to purchase additional shares of our stock in the secondary market. 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. Agenus and the other defendants will receive complete dismissals from the case. In October 2009, the Court entered an order granting final approval of the settlement, and subsequently judgment was entered. Various objectors have filed appeals. 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 June 30, 2011 for this action.

We may currently be, or may become a party, to other legal proceedings. 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,

Table of Contents

or liquidity, litigation is subject to inherent uncertainty. Furthermore, litigation consumes both cash and management attention.

Note F Recent Accounting Pronouncements

In December 2010, the FASB issued additional guidance on when to perform Step 2 of the goodwill impairment test for reporting units with zero or negative carrying amounts. The criteria for evaluating Step 1 of the goodwill impairment test and proceeding to Step 2 was amended for reporting units with zero or negative carrying amounts and requires performing Step 2 if qualitative factors indicate that it is more likely than not that a goodwill impairment exists. This guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2010. Upon the adoption of this guidance on January 1, 2011, we had a negative carrying value but determined there were no qualitative factors that indicated it was more likely than not that a goodwill impairment exists and accordingly, Step 2 of the goodwill impairment test was not required to be performed. The adoption of this amended guidance did not have any impact on our consolidated financial statements.

In June 2011, the FASB issued Accounting Standard Update No. 2011-05, Comprehensive Income (ASU 2011-05) which increases the prominence of other comprehensive income in financial statements. Under this standard, the components of net income and other comprehensive income must be presented in either one or two consecutive financial statements. The standard eliminates the option to present other comprehensive income in the statement of changes in equity. ASU 2011-05 is effective for fiscal years ending after December 15, 2011 and interim and annual periods thereafter. The standard should be applied retrospectively and early adoption is permitted. Adoption of this standard will impact only the presentation of our financial results.

Note G Fair Value Measurements

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

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 derivative liability at fair value. 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.

Table of Contents

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

| Description | June 30, 2011 | | December 31, 2010 | |
|----------------------|---|--|---|--|
| | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Unobservable Inputs (Level 3) | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Unobservable Inputs (Level 3) |
| Liabilities: | | | | |
| Derivative liability | | | | \$ 755 |

The following table presents our liabilities measured at fair value using significant unobservable inputs (Level 3), as of June 30, 2011 (amounts in thousands):

| | |
|--|-----------|
| Balance, December 31, 2010 | \$ 755 |
| Decrease for reclassification as Equity (see Note D) | (755) |
| Balance, June 30, 2011 | \$ |

As of June 30, 2011, and December 31, 2010, \$100,000 in principal of the 2005 Notes are outstanding with an estimated fair value of \$87,000 based on the most recent market transactions. As of June 30, 2011, and December 31, 2010, \$36.1 million and \$34.7 million in principal of the 2006 Notes are outstanding respectively. The fair value of the debt portion of the 2006 Notes exclusive of the conversion option at June 30, 2011, and December 31, 2010, is \$29.6 million and \$30.8 million, respectively, based on a present value methodology. The fair value of the embedded conversion option at June 30, 2011, is \$3.1 million.

Note H Equity

During the six months ended June 30, 2011, we issued and sold approximately 803,000 shares of our common stock in at the market offerings through our sales agents, McNicoll, Lewis & Vlak LLC and Wm Smith & Co. and raised net proceeds of approximately \$810,000 after deducting offering costs. We also issued and sold 530,000 shares based on the exercise of a purchase option under a subscription agreement dated December 13, 2010, and received net proceeds of \$477,000.

On March 3, 2011, we were notified by the Listing Qualifications Staff of Nasdaq (the Staff) that we are not in compliance with Nasdaq Marketplace Rule 5550(a)(2) (the Bid Price Requirement) because the bid price for our common stock had closed below the minimum \$1.00 per share requirement for 30 consecutive business days. In accordance with NASDAQ Listing Rule 5810(c)(3)(A), we have been provided 180 calendar days, or until August 30, 2011, to regain compliance with the Bid Price Requirement. Compliance can be achieved by maintaining a closing bid price of at least \$1.00 per share for at least 10 consecutive business days prior to the expiration of our 180 calendar day grace period. However, the Staff has the discretion to monitor the closing bid price for up to 20 business days, in certain circumstances, before deeming a company back in compliance. As of August 5, 2011, we have not achieved compliance with the Bid Price Requirement.

If compliance is not demonstrated within the applicable compliance period, the Staff would notify us that our securities will be subject to delisting from The NASDAQ Capital Market. However, we would have the right to appeal the Staff's determination to delist our securities to an independent NASDAQ Listing Qualifications Panel. During the appeal to the Panel, shares of our common stock would continue to trade on The Nasdaq Capital Market pending the issuance of the final Panel decision. The Panel has the discretion to grant us up to an additional 180 calendar days from the date of the Staff determination to delist. In assessing a request for continued listing, a Panel will consider whether a company is willing to effect a reverse stock split before the end of the requested additional compliance period, if such action is necessary for the company to regain compliance. A Panel will also consider whether the company appears likely to maintain compliance with all other applicable listing requirements during the requested additional compliance period and whether the company has an opportunity to achieve a \$1.00 per share price without effecting a reverse stock split.

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On June 15, 2011 our stockholders approved an amendment to our Amended and Restated Certificate of Incorporation to effect a reverse stock split at the discretion of our Board of Directors at an exchange ratio of not less than 1-for-2 or greater than 1-for-10. As a result, the Board has the authority, but not the obligation, in its sole discretion and without any further action on the part of the stockholders, to effect a reverse stock split at any time prior to the Company's

Table of Contents

2012 Annual Meeting of Stockholders that it believes to be advantageous to the Company and its stockholders, including, without limitation, for the purpose of maintaining compliance with The NASDAQ Capital Market listing requirements.

Table of Contents

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

Overview

Our current research and/or development activities are focused on developing technologies and product candidates to treat cancers and infectious diseases. Our core technology portfolio consists of our Heat Shock Protein (HSP) Platform (based on our HSP based technologies) and our Saponin Platform (based on our saponin adjuvant based technologies). Some of our key candidates from these technology platforms are highlighted below:

The Prophage Series of cancer vaccines: The Prophage Series of cancer vaccines is a patient specific application of our HSP Platform. We believe that the collective results from our clinical trials to date with product candidates from the Prophage Series indicate a favorable safety profile and signals of efficacy in multiple cancer types. In a registry following patients from a large randomized Phase 3 trial in non-metastatic renal cell carcinoma (RCC; kidney cancer), patients at intermediate-risk of recurrence who were in the treatment arm and received Prophage Series vaccine R-100 demonstrated an approximately 46 percent lower risk of death compared with those in the control arm (n = 362; $P < 0.05$; hazard ratio = 0.54). R-100 is approved for sale in this indication in Russia as Oncophage[®] vaccine (vitespen). Phase 2 trials are underway testing the Prophage Series vaccine candidates G-100 and G-200 in newly diagnosed and recurrent glioma, respectively. Although promising results have been observed to date there can be no assurance that we will successfully complete all clinical trials or obtain regulatory approvals for these products. Additional trials are under evaluation using combinations of potentially synergistic therapies, as well as in pediatric neurological tumors.

HerpV: HerpV is a recombinant therapeutic vaccine candidate for the treatment of genital herpes, which is also derived from our HSP Platform. It has completed Phase 1 testing, where it was shown to elicit both CD4 and CD8 positive T cell responses a first of its kind finding in genital herpes treatment. Because the product contains multiple antigens derived from the herpes simplex 2 virus (HSV-2), it may be applicable to a broader patient population and may have potential in managing outbreaks and disease transmission. We consider this to be a platform technology, since with the integration of heat shock proteins with antigenic peptides we could potentially create therapeutic vaccines for many infectious diseases. We are considering initiating a Phase 2 trial while continuing to seek potential partnership opportunities for this program.

QS-21 Stimulon[®] adjuvant (QS-21): QS-21, from our Saponin Platform, is an adjuvant, or a substance added to a vaccine or other immunotherapy that is intended to enhance immune response. The key licensees of QS-21 are GlaxoSmithKline (GSK) and JANSSEN Alzheimer Immunotherapy. There are approximately 15 vaccines containing QS-21 in clinical development by our licensees, including four in Phase 3 testing for malaria, melanoma, non-small cell lung cancer and shingles. The first products containing QS-21 are expected to be launched in the 2013-2014 timeframe, and we are entitled to royalties for at least 10 years post-launch. However, there is no guarantee that these products will obtain regulatory approval or, if so approved, will generate significant royalties, if any, or that we will be able to collect royalties, in the future. The pipeline of product candidates containing QS-21 is extraordinarily diverse, encompassing prophylactic as well as therapeutic vaccines for infectious diseases, multiple cancer types, and Alzheimer's disease. We do not incur clinical development costs for these products and are generally reimbursed for any related expenses by our licensees. QA-21, a veterinary grade of QS-21, is also within the Saponin Platform. QA-21 is in a commercial feline leukemia vaccine product of one of our licensees, and is under development for other veterinary applications.

We have incurred significant losses since our inception. As of June 30, 2011, we had an accumulated deficit of \$596.1 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 June 30, 2011, anticipated revenues, and the estimated proceeds from our license, supply, and collaborative agreements will be sufficient to satisfy our liquidity requirements into 2012. We expect to attempt to raise additional funds in advance of depleting our current funds. We may attempt to raise additional funds by: (1) out-licensing technologies or products to one or more third parties, (2) renegotiating third party agreements, (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 and/or one or more partnering arrangements for (1) our product, Oncophage and/or our other Prophage Series of cancer vaccines, (2) vaccines containing QS-21 under development by our licensees, and/or (3) potentially other product candidates, each of which will require additional capital.

Table of Contents

Our common stock is currently listed on the Nasdaq Capital Market under the symbol AGEN . In April 2009, we moved from The NASDAQ Global Market to The NASDAQ Capital Market as part of our plan to regain compliance with minimum market value requirements. On March 3, 2011, we were notified by the Listing Qualifications Staff of Nasdaq (the Staff) that we are not in compliance with Nasdaq Marketplace Rule 5550(a)(2) (the Bid Price Requirement) because the bid price for our common stock had closed below the minimum \$1.00 per share requirement for 30 consecutive business days. In accordance with Nasdaq Marketplace Rule 5810(c)(3)(A), we have been provided 180 calendar days, or until August 30, 2011, to regain compliance with the Bid Price Requirement. If compliance is not demonstrated within the applicable compliance period, the Staff will notify us that our securities will be delisted from the Nasdaq Capital Market. However, we may appeal the Staff 's determination to delist our securities to a Hearings Panel. During any appeal process, shares of our common stock would continue to trade on the Nasdaq Capital Market. There can be no assurance that we will meet the requirements for continued listing on the Nasdaq Capital Market or whether any appeal would be granted by the Hearings Panel. This is the third time we have been in non-compliance with the Bid Price Requirement since our move to The NASDAQ Capital Market.

Forward-Looking Statements

This Quarterly Report on Form 10-Q and other written and oral statements the Company makes from time to time contain certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the Exchange Act). You can identify these forward-looking statements by the fact they use words such as could, expect, anticipate, estimate, target, may, project, guidance, intend, plan, believe, will, potential, opportunity, future and other words and expressions in connection with any discussion of future operating or financial performance. One can also identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes to differ materially from current expectations. These statements are likely to relate to, among other things, our business strategy, our research and development, our product development efforts, our ability to commercialize our product candidates, our commercialization efforts in Russia, our prospects for initiating partnerships or collaborations, the timing of the introduction of products, the effect of new accounting pronouncements, uncertainty regarding our future operating results and our profitability, anticipated sources of funds as well as our plans, objectives, expectations, and intentions.

Although the Company believes it has been prudent in its plans and assumptions, no assurance can be given that any goal or plan set forth in forward-looking statements can be achieved and readers are cautioned not to place undue reliance on such statements, which speak only as of the date made. The Company undertakes no obligation to release publicly any revisions to forward-looking statements as a result of new information, future events, or otherwise.

We have included more detailed descriptions of these risks and uncertainties and other risks and uncertainties applicable to our business that the Company believes could cause actual results to differ materially from any forward-looking statements 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.

Oncophage[®] and Stimulon[®] are registered trademarks of Agenus Inc. and its subsidiaries. All rights reserved.

Historical Results of Operations

Quarter Ended June 30, 2011 Compared to the Quarter Ended June 30, 2010

Revenue: We generated revenue of \$786,000 and \$805,000 during the quarters ended June 30, 2011 and 2010, respectively. Revenue includes license fees and royalties earned, and in 2010, product revenue. In the quarters ended June 30, 2011 and 2010, we recorded revenue of \$385,000 and \$388,000, 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 expenses increased 7% to \$2.8 million for the quarter ended June 30, 2011 from \$2.6 million for the quarter ended June 30, 2010. The increase relates to our personnel related expenses necessary to support our products under development.

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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 4% to \$2.7 million for the quarter ended

Table of Contents

June 30, 2011 from \$2.8 million for the quarter ended June 30, 2010. This decrease is largely related to a reduction in our facility related expenses and our general cost containment efforts.

Non-Operating Income (Expense): Non-operating income of \$881,000 for the quarter ended June 30, 2010 consists of a \$1.1 million net gain on the extinguishment of a portion of our 5.25% convertible senior notes due February 2025 (the 2005 Notes) partially offset by the change in the fair value of our derivative liability of \$184,000. No similar activity occurred in 2011.

Interest Expense: Interest expense decreased to \$1.1 million for the quarter ended June 30, 2011 from \$1.2 million for the quarter ended June 30, 2010. This decrease is related to the repurchase of substantially all of our 2005 Notes during 2010. Interest on our 8% senior secured convertible notes due August 2014 (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 June 30, 2011 and 2010, interest expense included \$693,000 and \$641,000, respectively, related to the 2006 Notes.

Six Months Ended June 30, 2011 Compared to the Six Months Ended June 30, 2010

Revenue: We generated revenue of \$1.5 million and \$1.7 million during the six months ended June 30, 2011 and 2010, respectively. This decreased revenue in 2011 is due primarily to fewer shipments of QS-21 to our QS-21 licensees in the quarter ended June 30, 2011 as compared to the same quarter in 2010. In each of the six months ended June 30, 2011 and 2010, we recorded revenue of \$770,000, 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 expenses decreased 22% to \$5.6 million for the six months ended June 30, 2011 from \$7.3 million for the six months ended June 30, 2010. The decrease resulted from declines in spending 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 12% to \$5.5 million for the six months ended June 30, 2011 from \$6.3 million for the six months ended June 30, 2010. This decrease is largely related to a reduction in our facility related expenses and our general cost containment efforts.

Non-Operating Income (Expense): Non-operating income of \$563,000 for the six months ended June 30, 2010 consists of the net gain of \$1.1 million on the extinguishment of a portion of our 2005 Notes partially offset by the change in the fair value of our derivative liability of \$512,000. The change in our derivative liability is primarily due to an increase in our market value from December 31, 2009 to June 30, 2010.

Interest Expense: Interest expense decreased 18% to \$2.0 million for the six months ended June 30, 2011 from \$2.5 million for the six months ended June 30, 2010. This decrease is primarily related to the repurchase of substantially all of our 2005 Notes. Interest on our 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 six months ended June 30, 2011 and 2010, interest expense included \$1.4 million and \$1.3 million, respectively, which was paid in the form of issuing additional 2006 Notes.

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 quarter ended June 30, 2011, these research and development programs consisted largely of our Prophage Series vaccines as indicated in the following table (in thousands).

| Product | Six Months Ended | Year Ended December 31, | | | Prior to | Total | |
|---|--------------------------|-------------------------|-----------|-----------|-----------|------------|------------|
| | June 30, 2011 | 2010 | 2009 | 2008 | 2008 | | |
| Research and Development Program | | | | | | | |
| Heat Shock Proteins for Cancer | Prophage Series Vaccines | \$ 5,528 | \$ 10,960 | \$ 15,309 | \$ 17,156 | \$ 238,426 | \$ 287,379 |

Table of Contents

| | | | | | | | |
|---|-------|----------|-----------|-----------|-----------|------------|------------|
| Heat Shock Proteins for Infectious Diseases | HerpV | 79 | 644 | 262 | 1,377 | 16,071 | 18,433 |
| Vaccine adjuvant * | QS-21 | 32 | 1,185 | 1,071 | 648 | 9,500 | 12,436 |
| Other Research and Development Programs | | | 89 | 261 | 1,482 | 31,695 | 33,527 |
| Total Research and Development Expenses | | \$ 5,639 | \$ 12,878 | \$ 16,903 | \$ 20,663 | \$ 295,692 | \$ 351,775 |

* 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 Prophage Series vaccines 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 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 our Prophage Series vaccines is subject to evaluation and uncertainty, and because HerpV is an early-stage clinical development candidate, 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*Prophage Series of Cancer Vaccines*

We started enrolling patients in our first clinical trial studying a Prophage Series vaccine at Memorial Sloan-Kettering Cancer Center in New York, New York in November 1997. To date, we have treated nearly 850 cancer patients in our clinical trials. Because Prophage Series vaccines are novel therapeutic vaccines that are patient-specific, meaning derived from the patient's own tumor, they are experiencing a long development 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 the Prophage Series vaccines have a favorable safety profile. We also believe that available results from clinical trials suggest that treatment with Prophage Series vaccines can generate immunological and anti-tumor responses.

We initiated a Phase 3, multicenter, international trial for non-metastatic RCC into which the first patient was randomized in February 2001. As announced on March 24, 2006, the trial did not reach statistical significance in its primary endpoint of recurrence-free survival in the total patient population, though a positive trend was observed. During the protocol design process in 1999 and 2000, key opinion leaders were consulted, and the non-metastatic RCC patient population designated for enrollment in the trial was thought to be a relatively uniform group. In 2006, the Eastern Cooperative Oncology Group (ECOG) initiated a trial in adjuvant RCC with sorafenib and sunitinib that stratified their patient population into intermediate-risk, high-risk, and very high-risk recurrence categories. Using these ECOG defined criteria, analysis of the intermediate-risk patients (362 of the 604 eligible patients) in the trial showed a statistically significant difference in recurrence-free survival in favor of the Oncophage arm. In part because the intermediate-risk category was not prospectively delineated prior to the trial's initiation, the Food and Drug Administration (FDA) has indicated that, by itself, part I of our Phase 3 clinical trial in renal cell carcinoma is not sufficient to support a biologics license application (BLA) filing.

We opened a subsequent protocol that continued to follow patients from this trial 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 the vaccine, followed 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 (ASCO) 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 in the treatment arm compared with the control arm ($n = 362$; $P < 0.05$; hazard ratio = 0.54). Final analysis of this data has been completed and is under consideration for publication. There is no guarantee that the final data will uphold the results of our interim analysis.

Table of Contents

In addition to the patient registry, we commenced a small study in non-metastatic RCC to assess immune response in the intermediate-risk patient population. Patient enrollment has been closed. Any results of the final survival registry analysis and the RCC immunology trial will 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. Because, among other things, we have limited resources and minimal sales and marketing experience, commercialization of Oncophage has been slow, and only modest sales of Oncophage in Russia have occurred. 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 this approval we have been focusing our efforts in Russia on securing one or more distribution and/or partnering arrangements and related commercialization activities. The amount of any future revenue generated from the sale of Oncophage in Russia will depend on our ability to successfully execute on these efforts and identify and obtain adequate reimbursement, as well as on decisions of physicians and patients, among other factors. 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 marketing authorization application (MAA) to the European Medicines Agency (EMA) requesting conditional authorization of Oncophage in earlier-stage, localized kidney cancer. On November 20, 2009, we announced that the Committee for Medicinal Products for Human Use of the EMA formally adopted a ne