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AGENUS INC Form 10-Q May 06, 2011 Table of Contents

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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 March 31, 2011

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

For the transition period from

Commission File No. 000-29089

# Agenus Inc.

(Exact Name of Registrant as Specified in its Charter)

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 x 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 accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer " Accelerated filer x

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

Smaller reporting company "

Latin to be a beginning to the company of the company

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

Number of shares outstanding of the registrant s Common Stock as of May 3, 2011: 113,360,884 shares.

## Agenus Inc.

## **Quarterly Period Ended March 31, 2011**

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#### PART I FINANCIAL INFORMATION

#### Item 1 Financial Statements

#### AGENUS INC. AND SUBSIDIARIES

#### CONDENSED CONSOLIDATED BALANCE SHEETS

#### (Unaudited)

		March 31, 2011	D	December 31, 2010
ASSETS		2011		2010
Cash and cash equivalents	\$	10,630,571	\$	19,781,976
Short-term investments		4,998,799	·	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Accounts receivable		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		35,000
Inventories		26,432		26,432
Prepaid expenses		864,870		704,744
Other current assets		393,598		306,008
Total current assets		16,914,270		20,854,160
Plant and equipment, net of accumulated amortization and depreciation of \$25,144,541 and		10,511,270		20,03 1,100
\$24,993,225 at March 31, 2011 and December 31, 2010, respectively		5,663,516		6,194,465
Goodwill		2,572,203		2,572,203
Other long-term assets		1,277,131		1,285,831
		1,277,101		1,200,001
Total assets	\$	26,427,120	\$	30,906,659
Total assets	Ф	20,427,120	Ф	30,900,039
LIADH WEEGAND CTOOKHOLDEDG DEELCHT				
LIABILITIES AND STOCKHOLDERS DEFICIT	ф	146.061	Ф	146.061
Current portion, long-term debt	\$	146,061	\$	146,061
Current portion, deferred revenue		1,540,385		1,540,385
Accounts payable		450,458		698,554
Accrued liabilities		2,783,355		2,684,609
Other current liabilities		659,206		346,314
Total current liabilities		5,579,465		5,415,923
Convertible senior notes		28,722,005		34,050,033
Deferred revenue		3,227,060		3,612,156
Derivative liability (Note G)				755,000
Other long-term liabilities		1,355,714		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 March 31,				
2011 and December 31, 2010; liquidation value of \$31,817,625 at March 31, 2011		316		316
Series B2 convertible preferred stock; 3,105 shares designated, issued, and outstanding at March 31,				
2011 and December 31, 2010		31		31
Common stock, par value \$0.01 per share; 250,000,000 shares authorized; 113,574,657 and				
111,885,759 shares issued at March 31, 2011 and December 31, 2010, respectively		1,135,747		1,118,858
Additional paid-in capital		577,113,759		568,916,796
Treasury stock, at cost; 260,944 shares of common stock at March 31, 2011 and December 31, 2010		(324,792)		(324,792)
Accumulated deficit		(590,382,185)	(	(584,418,421)

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Total stockholders deficit	(12,457,124)	(14,707,212)
Total liabilities and stockholders deficit	\$ 26.427.120	\$ 30.906.659

See accompanying notes to unaudited condensed consolidated financial statements.

#### AGENUS INC. AND SUBSIDIARIES

# CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

#### (Unaudited)

#### **Quarter Ended**

		March 31,		
		2011		2010
Revenue	\$	671,881	\$	936,428
Operating expenses:				
Research and development	(2	2,815,376)	(4	1,631,284)
General and administrative	(2	2,878,939)	(3	3,566,097)
Operating loss	(5	5,022,434)	(7	7,260,953)
Other income (expense):		, , ,		, , ,
Non-operating income (expense)		6,867		(317,858)
Interest expense		(955,517)	(1	1,240,327)
Interest income		7,320		8,098
Net loss	(5	5,963,764)	(8	3,811,040)
Dividends on series A convertible preferred stock		(197,625)		(197,625)
Net loss attributable to common stockholders	\$ (6	5,161,389)	\$ (9	9,008,665)
	·			
Per common share data, basic and diluted:				
Net loss attributable to common stockholders	\$	(0.05)	\$	(0.10)
Weighted average number of common shares outstanding, basic and diluted	112	2,868,940	9(	),981,912

See accompanying notes to unaudited condensed consolidated financial statements.

#### AGENUS INC. AND SUBSIDIARIES

# CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

#### (Unaudited)

#### **Quarter Ended**

	March 31,	
	2011	2010
Cash flows from operating activities:	¢ (5.062.764)	¢ (0.011.040)
Net loss	\$ (5,963,764)	\$ (8,811,040)
Adjustments to reconcile net loss to net cash used in operating activities:	5(7.102	1 004 020
Depreciation and amortization	567,103	1,004,030
Intangible asset impairment		629,382
Change in fair value of derivative liability	(42.200	328,070
Share-based compensation	642,280	1,559,584
Non-cash interest expense	252,096	302,684
Gain on sale of property and equipment	6,003	1,501
Changes in operating assets and liabilities:	25,000	(207, 020)
Accounts receivable	35,000	(306,839)
Inventories	(160.106)	238,741
Prepaid expenses	(160,126)	(344,445)
Accounts payable	(248,096)	(464,264)
Deferred revenue	(385,096)	72,239
Accrued liabilities and other current liabilities	779,950	482,626
Other operating assets and liabilities	(170,086)	(582,421)
Net cash used in operating activities	(4,644,736)	(5,890,152)
Cash flows from investing activities:		
Proceeds from maturities of available-for-sale securities		10,000,000
Proceeds from sale of property and equipment	10,000	24,108
Purchases of available-for-sale securities	(4,998,799)	(9,997,346)
Purchases of plant and equipment	(43,458)	(47,186)
Net cash used in investing activities	(5,032,257)	(20,424)
Cash flows from financing activities:		
Deferred equity issuance costs		(46,491)
Net proceeds from sales of equity	680,621	
Proceeds from employee stock purchases	42,592	27,938
Payment of series A convertible preferred stock dividends	(197,625)	(197,625)
Net cash provided by (used in) financing activities	525,588	(216,178)
Net decrease in cash and cash equivalents	(9,151,405)	(6,126,754)
Cash and cash equivalents, beginning of period	19,781,976	20,066,817
Cash and cash equivalents, end of period	\$ 10,630,571	\$ 13,940,063

Non-cash financing activity:

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Convertible Note adjustment to equity for conversion option

\$ 5,580,124

Reclassification of derivative liability into equity

\$ 755,000

See accompanying notes to unaudited condensed consolidated financial statements.

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#### AGENUS INC. AND SUBSIDIARIES

#### NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

#### March 31, 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 biotechnologomany 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. Our Prophage Series of cancer vaccines has been tested in Phase 3 clinical trials for the treatment of renal cell carcinoma, the most common type of kidney cancer, as Oncophage, 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, and adjuvant renal cell carcinoma, validating immune response. Our product candidate portfolio includes (1) 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, and tuberculosis, and (2) HerpV, a therapeutic vaccine program tested in a Phase 1 clinical trial for the treatment of genital herpes. Further clinical development of HerpV will be pursued if a development partnership can be successfully established. 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 collabo

We have incurred significant losses since our inception. As of March 31, 2011, we had an accumulated deficit of \$590.4 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 as of March 31, 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 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 and requires a partner for further 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 March 31, 2011, we had debt outstanding of \$34.9 million in principal, including \$34.7 million in principal of our 8% senior secured convertible notes due August 2014 (the 2006 Notes) and \$100,000 in principal of our 5.25% convertible senior notes due February 2025 (the 2005 Notes). The 2005 Notes are subject to redemption at the option of the holders or us beginning February 1, 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) licensing technologies or products to one or more collaborative partners, (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 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.

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 three months ended March 31, 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 have 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, shares underlying the warrants outstanding or issuable to acquire 19,856,302 shares, the outstanding stock options to acquire 8,740,144 shares, the 1,022,057 nonvested shares, the 2,000,000 common shares underlying the 31,620 outstanding shares of series A convertible preferred stock, and the impact of conversion of our 2005 Notes are not included in the calculation of diluted net loss per common share.

#### 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 three months ended March 31, 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	1,643,416	1.05		
Forfeited	(112,456)	0.86		
Expired	(63,666)	2.30		
Outstanding at March 31, 2011	8,740,144	2.03	7.3	\$ 263,217
Vested or expected to vest at March 31, 2011	8,346,147	2.08	7.2	\$ 238,619
Exercisable at March 31, 2011	4,963,561	2.67		