AGENUS INC
Form 10-Q
November 04, 2015

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, 2015

or

o 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

Agenus Inc.

(exact name of registrant as specified in its charter)

Delaware	06-1562417
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

3 Forbes Road, Lexington, Massachusetts 02421

(Address of principal executive offices, including zip code)

Registrant’s telephone number, including area code:

(781) 674-4400

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 o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulations 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 x No o

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

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

Number of shares outstanding of the issuer's Common Stock as of October 30, 2015: 84,646,215 shares

Agenus Inc.

Nine Months Ended September 30, 2015

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements
AGENUS INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	September 30, 2015	December 31, 2014
ASSETS		
Cash and cash equivalents	$184,138,960	$25,714,519
Short-term investments	14,993,700	14,509,570
Inventories	88,200	95,700
Accounts Receivable	7,331,624	463,007
Prepaid expenses	1,953,486	1,247,548
Other current assets	437,311	639,957
Total current assets	208,943,281	42,670,301
Plant and equipment, net of accumulated amortization and depreciation of $29,351,331 and $28,369,982 at September 30, 2015 and December 31, 2014, respectively	7,829,693	5,996,687
Goodwill	18,139,991	17,869,023
Acquired intangible assets, net of accumulated amortization of $873,667 and $462,248 at September 30, 2015 and December 31, 2014, respectively	6,490,481	6,773,722
Other long-term assets	1,204,804	1,216,795
Total assets	$242,608,250	$74,526,528
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current portion, long-term debt	$146,061	$1,257,178
Current portion, deferred revenue	5,967,198	184,421
Accounts payable	3,091,199	1,710,946
Accrued liabilities	13,738,916	5,501,527
Other current liabilities	5,342,496	575,351
Total current liabilities	28,285,870	9,229,423
Long-term debt	110,553,452	4,769,359
Deferred revenue	15,498,207	3,009,568
Contingent royalty obligation	—	15,279,000
Contingent purchase price consideration	3,747,000	16,420,300
Other long-term liabilities	7,547,617	2,800,491
Commitments and contingencies		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $0.01 per share; 5,000,000 shares authorized:		
Series A-1 convertible preferred stock; 31,620 shares designated, issued, and outstanding at September 30, 2015 and December 31, 2014; liquidation value	316	316

of $32,164,572 at September 30, 2015		
Common stock, par value $0.01 per share; 140,000,000 shares authorized;		
84,646,215 and 62,720,065 shares issued at September 30, 2015 and		
December 31, 2014, respectively	846,462	627,201
Additional paid-in capital	841,041,405	715,667,633
Accumulated other comprehensive loss	(1,331,638)	(1,970,420)
Accumulated deficit	(763,580,441)	(691,306,343)
Total stockholders' equity	76,976,104	23,018,387
Total liabilities and stockholders' equity	$242,608,250	$74,526,528

See accompanying notes to unaudited condensed consolidated financial statements.

AGENUS INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Revenue:				
Research and development revenue	$ 6,848,194	$ 1,563,378	$ 17,178,191	$ 5,358,322
Total revenues	6,848,194	1,563,378	17,178,191	5,358,322
Operating expenses:				
Research and development	(18,502,063)	(5,284,607)	(52,495,316)	(14,979,844)
General and administrative	(6,407,902)	(4,919,675)	(19,910,650)	(16,209,790)
Contingent purchase price consideration fair value adjustment	6,994,000	969,000	(7,326,700)	(164,000)
Operating loss	(11,067,771)	(7,671,904)	(62,554,475)	(25,995,312)
Other (expense) income:				
Non-operating (expense) income	(653,376)	(127,367)	(7,356,139)	10,449,462
Interest expense, net	(1,401,102)	(310,080)	(2,363,484)	(962,015)
Net loss	(13,122,249)	(8,109,351)	(72,274,098)	(16,507,865)
Dividends on Series A-1 convertible preferred stock	(50,780)	(51,159)	(152,099)	(153,292)
Net loss attributable to common stockholders	$ (13,173,029)	$ (8,160,510)	$ (72,426,197)	$ (16,661,157)
Per common share data:				
Basic and diluted net loss attributable to common stockholders	$ (0.16)	$ (0.13)	$ (0.95)	$ (0.28)
Weighted average number of common shares outstanding:				
Basic and diluted	84,569,118	62,831,541	75,935,985	58,710,338
Other comprehensive income (loss):				
Foreign currency translation gain (loss)	$ (680,993)	$ (1,294,720)	$ 625,132	$ (1,161,036)
Unrealized gain on investments	7,760	1,863	13,650	3,816
Other comprehensive income (loss)	(673,233)	(1,292,857)	638,782	(1,157,220)
Comprehensive loss	$ (13,846,262)	$ (9,453,367)	$ (71,787,415)	$ (17,818,377)

See accompanying notes to unaudited condensed consolidated financial statements.

AGENUS INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine months ended September 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	$(72,274,098)	$(16,507,865)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,403,324	1,019,073
Share-based compensation	5,218,479	3,700,518
Non-cash interest expense	1,643,417	461,653
Loss on disposal of assets	—	1,150
Change in fair value of contingent obligations	14,190,000	(10,652,557)
In-process research and development purchase	12,245,230	—
Loss on extinguishment of debt	154,117	—
Change in fair value of assumed convertible notes	—	(205,143)
Changes in operating assets and liabilities:		
Accounts receivable	(7,232,669)	1,200
Inventories	7,500	(95,700)
Prepaid expenses	(693,981)	(425,485)
Accounts payable	1,266,219	35,207
Deferred revenue	18,465,694	(2,695,737)
Accrued liabilities and other current liabilities	8,390,007	(2,021,879)
Other operating assets and liabilities	(10,367,586)	(341,034)
Net cash used in operating activities	(27,584,347)	(27,726,599)
Cash flows from investing activities:		
Cash acquired in acquisition	—	514,470
Purchases of plant and equipment	(2,818,429)	(1,105,472)
Purchases of available-for-sale securities	(15,006,730)	(14,517,644)
Proceeds from sale of available-for-sale securities	14,534,486	—
Net cash used in investing activities	(3,290,673)	(15,108,646)
Cash flows from financing activities:		
Net proceeds from sale of equity	109,669,980	56,792,252
Proceeds from employee stock purchases and option exercises	1,963,738	150,140
Financing of plant and equipment	—	(39,156)
Proceeds from issuance of long-term debt	109,000,000	—
Debt issuance costs	(1,774,323)	—
Payments of debt	(1,111,112)	(2,500,000)
Payment of contingent purchase price consideration	(8,380,483)	—
Payment of preferred stock dividends	—	(460,963)
Payment of contingent royalty obligation	(20,000,000)	(400,000)
Net cash provided by financing activities	189,367,800	53,542,273
Effect of exchange rate changes on cash	(68,339)	327,128
Net increase in cash and cash equivalents	158,424,441	11,034,156
Cash and cash equivalents, beginning of period	25,714,519	27,351,969

Cash and cash equivalents, end of period	$184,138,960	$38,386,125
Supplemental cash flow information:		
Cash paid for interest	$770,538	$531,863
Supplemental disclosures - non-cash activities:		
Purchases of plant and equipment in accounts payable and accrued liabilities	111,903	292,106
Issuance of common stock, $0.01 par value, issued in connection with the settlement of the contingent royalty obligation	2,142,000	—
Issuance of common stock, $0.01 par value, issued in connection with the acquisition of the SECANT Yeast Display technology	3,000,000	—
Issuance of common stock, $0.01 par value, for acquisition of 4-Antibody AG	—	10,102,259
Issuance of common stock, $.01 par value, in connection with payment of the contingent purchase price obligation	344,550	—
Contingent purchase price consideration issued in connection with the acquisition of 4-Antibody AG	—	9,721,000
Issuance of common stock, $0.01 par value, as payment of long-term debt	—	953,765

See accompanying notes to unaudited condensed consolidated financial statements.

AGENUS INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

Note A - Business, Liquidity and Basis of Presentation

Agenus Inc. (including its subsidiaries, also referred to as “Agenus,” the “Company,” “we,” “us,” and “our”) is an immunology company discovering and developing novel checkpoint modulators, vaccines and adjuvants to treat cancer and other diseases. Our approaches are driven by three platform technologies:

- our antibody platforms, including our proprietary Retrocyte Display™, SECANT® yeast display, our phage display technologies, and our antibody programs, including checkpoint modulators, or CPMs;
- our heat shock protein (HSP)-based vaccines; and
- our saponin-based vaccine adjuvants, principally our QS-21 Stimulon® adjuvant, or QS-21 Stimulon.

We have a portfolio of programs in pre-clinical and clinical stages, including a series of CPMs in investigational new drug (IND)-enabling studies, our Prophage vaccine, a HSP-based autologous vaccine candidate for glioblastoma multiforme, or GBM, a form of brain cancer, and a number of advanced QS-21 Stimulon-containing vaccine candidates in late stage development by our partner, GlaxoSmithKline plc (GSK).

For the treatment of cancer, our programs aim to stimulate the immune system to recognize and eradicate cancer cells and disable the mechanisms that cancer cells employ to evade detection and destruction by the immune system. Because of the breadth of our portfolio, we have the ability to combine our proprietary vaccines with a portfolio of checkpoint modulating antibodies against major checkpoint targets to explore and optimize cancer treatments. Our strategy is to develop these agents either alone or in combinations to yield best-in-class treatments. We assess the development, commercialization and/or partnering strategies with respect to each of our internal product candidates periodically based on several factors, including clinical trial results, competitive positioning and funding requirements and resources.

Agenus’ core technologies include Retrocyte Display, a powerful proprietary platform designed to effectively discover and optimize novel, fully human and humanized monoclonal antibodies against antigens of interest. Our Retrocyte Display technology is applied to the discovery and development of antibodies, including those targeting significant checkpoint targets. Agenus and its partners currently have pre-clinical programs targeting GITR, OX40, CTLA-4, LAG-3, TIM-3, PD-1, CEACAM1 and other undisclosed check-point programs. In April 2015, we expanded our antibody discovery platform through the acquisition of key antibody assets from Celexion, LLC (Celexion); see Note L. Among the acquired assets was the SECANT yeast display platform for the generation of novel monoclonal antibodies and efficient integration of drug targets such as CPMs.

On January 9, 2015 and effective February 19, 2015, we entered into a broad, global alliance with Incyte Corporation and a wholly-owned subsidiary thereof (collectively "Incyte") to pursue the discovery and development of CPMs, initially targeting GITR, OX40, TIM-3 and LAG-3 in the fields of hematology and oncology. We also began collaborating with Merck Sharp & Dohme Corp in April 2014 to discover antibodies against two undisclosed CPM targets. We anticipate initiating clinical trials with the first of our CPM antibody candidates in 2016.

We have also been advancing a series of HSP-based vaccines to treat cancer and infectious disease. In June 2015, at the American Society of Clinical Oncology (ASCO) meeting, we reported positive results from a Phase 2 clinical trial with our Prophage vaccine, which showed that patients with newly-diagnosed GBM who were treated with a combination of our Prophage vaccine and standard of care showed substantial improvement both in progression-free

survival and median overall survival, as compared to historical control data. The most significant clinical improvements were seen in patients with less elevated PD-L1 expression in peripheral blood monocytes. These observations suggested that while some patients may derive the greatest benefit from standard of care and the Prophage vaccine alone, patients with more elevated PD-L1 expression on peripheral monocytes may benefit from a combination of Prophage in addition to checkpoint modulators PD-1 or PD-L1. We are currently exploring advancing our Prophage vaccine into well-controlled randomized trials designed to study Prophage versus the standard of care. In addition, efforts are currently underway to conduct adequately controlled and randomized combination studies using Prophage while we simultaneously explore partnership opportunities to license Prophage. In 2014, we also reported positive results from a Phase 2 clinical trial with our HerpV vaccine candidate for genital herpes, and while we do not expect to advance into a Phase 3 clinical trial for genital herpes, we are currently in the process of evaluating the broader application of our HSP peptide-based vaccines.

The Company’s QS-21 Stimulon adjuvant is a key component in several of GSK’s pre-clinical and clinical stage vaccine programs, which target prophylactic or therapeutic impact in a variety of infectious diseases and cancer. In December 2014, GSK reported that its Phase 3 clinical trial with shingles vaccine candidate, HZ/su, using our QS-21 Stimulon adjuvant, met its primary

endpoint, reducing the risk of shingles by 97.2% in adults aged 50 years and older compared to placebo. GSK also reported positive Phase 3 clinical trial results in October 2013 for its malaria vaccine candidate using QS-21 Stimulon, Mosquirix™ (RTS,S), which recently received a positive opinion from the Committee for Medicinal Products for Human Use of the European Medicines Agency. In September 2015, we monetized a portion of the future royalties we are contractually entitled to receive from GSK from sales of its shingles and malaria vaccines through a Note Purchase Agreement and received net proceeds of approximately $98.2 million; refer to Note E for additional information. QS-21 Stimulon is also the subject of an out-license agreement with Janssen Sciences Ireland Uc for use in a vaccine for Alzheimer's disease.

Our business activities include product research and development, intellectual property prosecution, manufacturing, regulatory and clinical affairs, corporate finance and development activities, 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, 2015, we had an accumulated deficit of $763.6 million. To date, we have financed our operations primarily through the sale of equity and debt securities. We believe that, based on our current plans and activities, our working capital resources at September 30, 2015 will be sufficient to satisfy our liquidity requirements into the first half of 2018.

We may attempt to raise additional funds by: (1) pursuing collaboration, out-licensing and/or partnering opportunities for our portfolio programs and product candidates with 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 substantial out-licensing or partnering arrangements for our antibody discovery platforms, CPM antibody programs, HSP-based vaccines, and vaccines containing QS-21 Stimulon under development by our licensees. Our long-term success will also be dependent on the successful identification, development and commercialization of potential other product candidates, each of which will require additional capital with no certainty of timing or probability of success. 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.

Our 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 research and development and significant additional expenditures will be required if we start new clinical 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, number of patients, and trial sponsorship. The process of obtaining and maintaining regulatory approvals for new therapeutic products is lengthy, expensive, and uncertain. Because our CPM antibody programs are pre-clinical and the further development of our HSP-based vaccines is subject to evaluation and uncertainty, we are unable to reliably estimate the cost of completing our research and development programs or the timing for bringing such programs to various markets or substantial partnering or out-licensing arrangements. Therefore, we cannot predict if or when material cash inflows from operating activities are likely to commence. We will continue to adjust other spending as needed in order to preserve liquidity. Active programs involving QS-21 Stimulon depend on our collaboration partners or licensees successfully completing clinical trials, successfully manufacturing QS-21 Stimulon to meet demand, obtaining regulatory approvals and successfully commercializing product candidates containing QS-21 Stimulon.

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. 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 our 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 reclassifications have been made to previously reported amounts to conform to the current presentation. Operating results for the nine months ended September 30, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015. 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, 2014 filed with the Securities and Exchange Commission (the “SEC”).

For our foreign subsidiaries the local currency is the functional currency. Assets and liabilities of our foreign subsidiaries are translated into U.S. dollars using rates in effect at the balance sheet date while revenues and expenses are translated into U.S. dollars using average exchange rates during the period. The cumulative translation adjustment resulting from changes in exchange rates are included in the consolidated balance sheets as a component of accumulated other comprehensive loss in total stockholders’ equity.

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 net 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, or DDCP). Diluted net loss per common share is calculated by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding (including common shares issuable under our DDCP) plus the dilutive effect of outstanding instruments such as warrants, stock options, nonvested shares, and convertible preferred stock. Because we reported a net loss attributable to common stockholders for all periods presented, diluted net loss per common share is the same as basic net 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 because they would be anti-dilutive:

	Nine months ended September 30,	
	2015	2014
Warrants	4,351,450	2,951,450
Stock options	8,226,791	6,841,400
Nonvested shares	1,734,821	78,828
Convertible preferred stock	333,333	333,333

Note C - Investments

Cash equivalents and short-term investments consisted of the following as of September 30, 2015 and December 31, 2014 (in thousands):

	September 30, 2015		December 31, 2014	
	Cost	Estimated Fair Value	Cost	Estimated Fair Value
Institutional Money Market Funds	$172,811	$172,811	$25,149	$25,149
U.S. Treasury Bills	14,971	14,994	14,508	14,510
Total	$187,782	$187,805	$39,657	$39,659

For the nine months ended September 30, 2015, we received proceeds of approximately $14.5 million from the sale of available-for-sale securities. No proceeds from the maturity of available-for-sale securities were received for the year ended December 31, 2014. Gross realized gains included in net loss as a result of the sale of available-for-sale securities were immaterial for the nine months ended September 30, 2015. As a result of the short-term nature of our investments, there were minimal unrealized holding gains or losses as of September 30, 2015 and December 31, 2014.

Of the investments listed above, $172.8 million and $25.1 million have been classified as cash equivalents and $15.0 million and $14.5 million as short-term investments on our condensed consolidated balance sheet as of September 30, 2015 and December 31, 2014, respectively.

Note D - Goodwill and Acquired Intangible Assets

The following table sets forth the changes in the carrying amount of goodwill for the nine months ended September 30, 2015 (in thousands):

Balance, December 31, 2014	$17,869
Foreign currency translation adjustment	271
Balance, September 30, 2015	$18,140

Acquired intangible assets consisted of the following at September 30, 2015 (in thousands):

	Amortization period (years)	Gross carrying amount	Accumulated amortization	Net carrying amount
Intellectual Property	15 years	$ 4,425	$ (479)	$ 3,946
Trademarks	4.5 years	829	(300)	529
Other	3 years	175	(95)	80
In-process research and development	Indefinite	1,935	—	1,935
Total		$ 7,364	$ (874)	$ 6,490

The weighted average amortization period of our finite-lived intangible assets is 13 years. Amortization expense related to acquired intangibles is estimated at $134,000 for the remainder of 2015, $512,000 for each of the years ending 2016 and 2017, $410,000 for the year ending 2018, $295,000 for the year ending 2019, and $299,000 for each of the years ending 2020-2029.

The acquired in-process research and development ("IPR&D") asset relates to the pre-clinical CPM antibody programs acquired with our acquisition of 4-Antibody AG (“4-AB”) 4-AB in February 2014. IPR&D acquired in a business combination is capitalized at fair value until the underlying project is completed and is subject to impairment testing at least annually. Once the project is completed, the carrying value of IPR&D is amortized over the estimated useful life of the asset. Post-acquisition research and development expenses related to the acquired IPR&D are expensed as incurred.

Note E - Debt

Debt obligations consisted of the following as of September 30, 2015 and December 31, 2014 (in thousands):

Debt instrument	Principal at September 30, 2015	Non-cash Interest	Unamortized Debt Issuance Costs	Unamortized Debt Discount	Balance at September 30, 2015
Current Portion:					
Debentures	$ 146	$ —	$ —	$ —	$ 146
Long-term Portion:					
2015 Subordinated Notes	14,000	—	—	(2,510)	11,490
Note Purchase Agreement	100,000	825	(1,514)	(248)	99,063
Total long-term	$ 114,000	$ 825	$ (1,514)	$ (2,758)	$ 110,553
Total	$ 114,146	$ 825	$ (1,514)	$ (2,758)	$ 110,699
Debt instrument	Principal at December 31,	Non-cash Interest	Unamortized Debt	Unamortized Debt	Balance at December

	2014		Issuance Costs	Discount	31, 2014
Current Portion:					
Debentures	$ 146	$ —	$ —	$ —	$ 146
SVB Loan	1,111	—	—	—	1,111
Total current	$ 1,257	$ —	$ —	$ —	$ 1,257
Long-term Portion:					
2013 Notes	5,000	—	—	(231	