AGENUS INC
Form 10-Q
August 04, 2016

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 June 30, 2016

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 July 29, 2016: 86,999,302 shares

Agenus Inc.

Six Months Ended June 30, 2016

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements
AGENUS INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	June 30, 2016	December 31, 2015
ASSETS		
Cash and cash equivalents	$73,397,742	$136,702,873
Short-term investments	49,895,350	34,964,730
Inventories	88,200	88,200
Accounts Receivable	9,417,170	9,800,342
Prepaid expenses	2,763,343	1,956,941
Other current assets	506,712	582,280
Total current assets	136,068,517	184,095,366
Property, plant and equipment, net of accumulated amortization and depreciation of $30,771,823 and $29,488,793 at June 30, 2016 and December 31, 2015, respectively	18,223,742	15,310,623
Goodwill	23,014,532	22,792,778
Acquired intangible assets, net of accumulated amortization of $2,128,318 and $987,394 at June 30, 2016 and December 31, 2015, respectively	17,723,785	18,759,662
Other long-term assets	1,423,690	1,270,055
Total assets	$196,454,266	$242,228,484
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current portion, long-term debt	$146,061	$146,061
Current portion, deferred revenue	2,629,137	3,829,371
Accounts payable	5,022,132	4,488,561
Accrued liabilities	19,577,112	14,165,816
Other current liabilities	5,688,409	6,304,281
Total current liabilities	33,062,851	28,934,090
Long-term debt, net of current portion	122,125,072	114,326,489
Deferred revenue, net of current portion	13,636,238	15,065,754
Contingent purchase price consideration	5,987,000	5,608,000
Other long-term liabilities	4,765,961	7,566,601
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 June 30, 2016 and December 31, 2015; liquidation value of $32,317,394 at June 30, 2016	316	316
	869,154	863,907

Common stock, par value $0.01 per share; 240,000,000 and 140,000,000 shares authorized at June 30, 2016 and December 31, 2015, respectively; 86,915,435 and 86,390,697 shares issued at June 30, 2016 and December 31, 2015, respectively		
Additional paid-in capital	856,107,365	851,103,934
Treasury stock, at cost; 3,067 shares at June 30, 2016	(12,881)	-
Accumulated other comprehensive loss	(1,658,055)	(2,053,143)
Accumulated deficit	(838,428,755)	(779,187,464)
Total stockholders' equity	16,877,144	70,727,550
Total liabilities and stockholders' equity	$196,454,266	$242,228,484

See accompanying notes to unaudited condensed consolidated financial statements.

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AGENUS INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenue:				
Service revenue	$—	$—	$147,456	$—
Research and development	6,592,285	6,376,699	12,403,705	10,329,997
Total revenues	6,592,285	6,376,699	12,551,161	10,329,997
Operating expenses:				
Research and development	(22,361,786)	(24,773,110)	(47,400,264)	(33,993,253)
General and administrative	(7,117,232)	(8,015,639)	(16,348,753)	(13,502,748)
Contingent purchase price consideration fair value adjustment	(721,000)	(6,783,000)	(379,000)	(14,320,700)
Operating loss	(23,607,733)	(33,195,050)	(51,576,856)	(51,486,704)
Other expense:				
Non-operating expense	(508,794)	(6,649,818)	(185,711)	(6,702,763)
Interest expense, net	(4,203,352)	(565,519)	(8,335,815)	(962,382)
Net loss	(28,319,879)	(40,410,387)	(60,098,382)	(59,151,849)
Dividends on Series A-1 convertible preferred stock	(51,021)	(50,700)	(101,962)	(101,320)
Net loss attributable to common stockholders	$(28,370,900)	$(40,461,087)	$(60,200,344)	$(59,253,169)
Per common share data:				
Basic and diluted net loss attributable to common stockholders	$(0.33)	$(0.53)	$(0.69)	$(0.83)
Weighted average number of common shares outstanding:				
Basic and diluted	86,964,777	76,374,824	86,825,646	71,547,783
Other comprehensive (loss) income:				
Foreign currency translation (loss) gain	$(143,543)	$541,714	$395,088	$1,306,035
Unrealized gain on investments	-	5,980	-	5,980
Other comprehensive (loss) gain	(143,543)	547,694	395,088	1,312,015
Comprehensive loss	$(28,514,443)	$(39,913,393)	$(59,805,256)	$(57,941,154)

See accompanying notes to unaudited condensed consolidated financial statements.

AGENUS INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Six Months Ended June 30, 2016	2015
Cash flows from operating activities:		
Net loss	$(60,098,382)	$(59,151,849)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,519,873	885,497
Share-based compensation	6,317,596	4,445,307
Non-cash interest expense	7,983,749	502,692
In-process research and development purchase	—	12,245,230
Change in fair value of contingent obligations	379,000	20,688,700
Loss on extinguishment of debt	—	154,117
Changes in operating assets and liabilities:		
Accounts receivable	434,257	(3,952,597)
Inventories	—	7,500
Prepaid expenses	(802,505)	(392,932)
Accounts payable	474,526	797,838
Deferred revenue	(2,629,753)	20,953,635
Accrued liabilities and other current liabilities	5,385,328	3,511,216
Other operating assets and liabilities	11,452	(10,268,265)
Net cash used in operating activities	(40,024,859)	(9,573,911)
Cash flows from investing activities:		
Purchases of plant and equipment	(3,164,423)	(1,523,511)
Purchases of held-to-maturity securities	(49,895,350)	(14,997,990)
Proceeds from securities held-to-maturity	35,000,000	14,534,486
Net cash used in investing activities	(18,059,773)	(1,987,015)
Cash flows from financing activities:		
Net proceeds from sale of equity	—	109,683,304
Proceeds from employee stock purchases and option exercises	471,357	1,682,235
Purchase of treasury shares to satisfy tax withholdings	(667,050)	—
Proceeds from issuance of long-term debt	—	9,000,000
Payments of debt	—	(1,111,112)
Payment of contingent purchase price consideration	—	(8,386,026)
Payment under a purchase agreement for in-process research and development	(5,000,000)	—
Payment of capital lease obligation	(24,110)	—
Net cash (used in) provided by financing activities	(5,219,803)	110,868,401
Effect of exchange rate changes on cash	(696)	(357,475)
Net (decrease) increase in cash and cash equivalents	(63,305,131)	98,950,000
Cash and cash equivalents, beginning of period	136,702,873	25,714,519
Cash and cash equivalents, end of period	$73,397,742	$124,664,519
Supplemental cash flow information:		
Cash paid for interest	$555,397	$487,325
Supplemental disclosures - non-cash activities:		
Purchases of plant and equipment in accounts payable and	62,219	104,151

accrued liabilities		
Issuance of common stock, $0.01 par value, in connection with the acquisition of the SECANT yeast display technology	—	3,000,000
Contingent purchase price consideration in connection with the acquisition of 4-Antibody AG	—	344,550

See accompanying notes to unaudited condensed consolidated financial statements.

AGENUS INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2016

Note A - Business, Liquidity and Basis of Presentation

Agenus Inc. (including its subsidiaries, collectively referred to as “Agenus,” the “Company,” “we,” “us,” and “our”) is an immuno-oncology company focused on the discovery and development of revolutionary new treatments that engage the body’s immune system to benefit patients suffering from cancer. We are developing a comprehensive immuno-oncology portfolio driven by the following platforms and programs, which we intend to utilize individually and in combination:

- our antibody discovery platforms, including our Retrocyte Display™, SECANT® yeast display, and phage display technologies designed to produce quality human antibodies;
- our antibody candidate programs, including our checkpoint modulator (“CPM”) programs;
- our vaccine programs, including Prophage™, AutoSynVax™ and PhosphoSynVax™; and
- our saponin-based vaccine adjuvants, principally our QS-21 Stimulon® adjuvant (“QS-21 Stimulon”).

We have a portfolio of programs in various stages of development, including a series of antibodies in discovery and pre-clinical and clinical development, our Prophage vaccine, a Heat Shock Protein (“HSP”)-based autologous vaccine candidate for a form of brain cancer that has successfully completed Phase 2 trials, and a number of advanced QS-21 Stimulon-containing vaccine candidates in late stage development by our licensee, GlaxoSmithKline (“GSK”).

Our core antibody technologies include our antibody discovery platforms that are designed to effectively discover and produce quality human antibodies against antigens of interest. We and our partners currently have programs targeting GITR, OX40, CTLA-4, LAG-3, TIM-3, PD-1, CEACAM1 and other undisclosed targets.

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 June 30, 2016, we had an accumulated deficit of $838.4 million. Since our inception, we have financed our operations primarily through the sale of equity and convertible and other notes, and interest income earned on cash, cash equivalents, and short-term investment balances. We believe that, based on our current plans and activities, our cash, cash equivalents and short-term investments balance of $123.3 million as of June 30, 2016 will be sufficient to satisfy our liquidity requirements through the first half of 2017.

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. Operating results for the six months ended June 30, 2016, are not necessarily indicative of the results that may be expected for the year ending December 31, 2016. 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, 2015 filed with the Securities and Exchange Commission (the “SEC”) on March 15, 2016.

Effective June 14, 2016, our certificate of incorporation was amended to increase the number of authorized shares of common stock from 140,000,000 to 240,000,000.

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 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 DDCP) 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, 2016 and 2015, as they would be anti-dilutive:

	Six Months Ended June 30,	
	2016	2015
Warrants	4,351,450	4,351,450
Stock options	11,659,125	7,908,570
Nonvested shares	1,999,294	46,705
Convertible preferred stock	333,333	333,333

Note C - Investments

Cash equivalents and short-term investments consisted of the following as of June 30, 2016 and December 31, 2015 (in thousands):

	June 30, 2016		December 31, 2015	
	Cost	Estimated Fair Value	Cost	Estimated Fair Value
Institutional money market funds	$32,464	$32,464	$106,370	$106,370
U.S. Treasury Bills	84,873	84,873	54,945	54,961
Total	$117,337	$117,337	$161,315	$161,331

For the six months ended June 30, 2016, we received proceeds of approximately $40.0 million from the maturity of U.S. Treasury Bills classified as cash equivalents and $35.0 million from securities held-to-maturity. As a result of the short-term nature of our investments, there were minimal unrealized holding gains or losses for the three and six months ended June 30, 2016 and 2015.

Of the investments listed above, $67.4 million and $126.4 million have been classified as cash equivalents and $49.9 million and $35.0 million as short-term investments on our condensed consolidated balance sheets as of June 30, 2016 and December 31, 2015, respectively.

Note D - Goodwill and Acquired Intangible Assets

The following table sets forth the changes in the carrying amount of goodwill for the six months ended June 30, 2016 (in thousands):

Balance, December 31, 2015	$22,793
Foreign currency translation adjustment	222
Balance, June 30, 2016	$23,015

Acquired intangible assets consisted of the following as of June 30, 2016 and December 31, 2015 (in thousands):

	As of June 30, 2016			
	Amortization period (years)	Gross carrying amount	Accumulated amortization	Net carrying amount
Intellectual property	7-15 years	$ 16,536	$ (1,484)	$ 15,052
Trademarks	4.5 years	824	(435)	389
Other	2-6 years	570	(209)	361
In-process research and development	Indefinite	1,922	-	1,922
Total		$ 19,852	$ (2,128)	$ 17,724

	As of December 31, 2015			
	Amortization period (years)	Gross carrying amount	Accumulated amortization	Net carrying amount
Intellectual property	7-15 years	$ 16,472	$ (541)	$ 15,931
Trademarks	4.5 years	812	(339)	473
Other	2-6 years	567	(107)	460
In-process research and development	Indefinite	1,896	—	1,896
Total		$ 19,747	$ (987)	$ 18,760

The weighted average amortization period of our finite-lived intangible assets is 9 years. Amortization expense related to acquired intangibles is estimated at $1.3 million for the remainder of 2016, $2.2 million for the year ending 2017, $2.1 million for the year ending 2018 and $1.9 million for each of the years ending 2019 and 2020.

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 in February 2014. IPR&D acquired in a business combination is capitalized at fair value and is subject to impairment testing at least annually until the underlying project is completed. 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 June 30, 2016 and December 31, 2015 (in thousands):

Debt instrument	Principal at	Non-cash	Unamortized	Unamortized

	June 30, 2016	Interest	Debt Issuance Costs	Debt Discount	Balance at June 30, 2016
Current Portion:					
Debentures	$ 146	$ —	$ —	$ —	$ 146
Long-term Portion:					
2015 Subordinated Notes	14,000	—	—	(1,818)	12,182
Note Purchase Agreement	100,000	11,587	(1,411)	(233)	109,943
Total long-term	$ 114,000	$ 11,587	$ (1,411)	$ (2,051)	$ 122,125
Total	$ 114,146	$ 11,587	$ (1,411)	$ (2,051)	$ 122,271

Debt instrument	Principal at December 31, 2015	Non-cash Interest	Unamortized Debt Issuance Costs	Unamortized Debt Discount	Balance at December 31, 2015
Current Portion:					
Debentures	$ 146	$ —	$ —	$ —	$ 146
Long-term Portion:					
2015 Subordinated Notes	14,000	—	—		