Aeglea BioTherapeutics, Inc.
Form 10-Q
August 09, 2018

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number: 001-37722

AEGLEA BIOTHERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	46-4312787
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
901 S. MoPac Expressway Barton Oaks Plaza One Suite 250 Austin, TX 78746 (Address of principal executive offices including zip code)	

Registrant's telephone number, including area code: (512) 942-2935

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth 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	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of August 3, 2018, the registrant had 21,995,032 shares of common stock, $0.0001 par value per share, outstanding.

AEGLEA BIOTHERAPEUTICS, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED JUNE 30, 2018

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NOTE ABOUT FORWARD-LOOKING STATEMENTS

This quarterly report contains forward-looking statements. All statements other than statements of historical fact are "forward-looking statements" for purposes of this Quarterly Report on Form 10-Q. These forward-looking statements may include, but are not limited to, statements regarding our future results of operations and financial position, business strategy, market size, potential growth opportunities, clinical development activities, efficacy and safety profile of our product candidates, our ability to maintain and recognize the benefits of certain designations received by product candidates, results of pre-clinical studies and clinical trials, and the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates. The words "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "predict," "target," "intend," "could," "would," "should," "project," "plan," "expect," and expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "Risk Factors" and elsewhere in this quarterly report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this quarterly report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations, except as required by law.

As used in this Quarterly Report on Form 10-Q, the terms "Aeglea," "the Company," "we," "us," and "our" refer to Aeglea BioTherapeutics, Inc. and, where appropriate, its consolidated subsidiaries, unless the context indicates otherwise.

PART I. – FINANCIAL INFORMATION

Item 1. Financial Statements
Aeglea BioTherapeutics, Inc.

Condensed Consolidated Balance Sheets

(Unaudited)

(In thousands, except share and per share amounts)

	June 30, 2018	December 31, 2017
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$20,579	$12,817
Marketable securities	51,614	37,482
Accounts receivable - grant	4,281	3,078
Prepaid expenses and other current assets	2,414	1,614
Total current assets	78,888	54,991
Property and equipment, net	776	854
Other non-current assets	49	232
TOTAL ASSETS	$79,713	$56,077
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$952	$389
Deferred revenue	—	20
Accrued and other current liabilities	5,223	5,220
Total current liabilities	6,175	5,629
Other non-current liabilities	91	111
TOTAL LIABILITIES	6,266	5,740
Commitments and Contingencies (Note 9)		
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of June 30, 2018 and December 31, 2017; no shares issued and outstanding as of June 30, 2018 and December 31, 2017	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized as of June 30, 2018 and December 31, 2017; 21,908,192 shares and 16,670,188 shares issued and outstanding as of June 30, 2018 and	2	2

December 31, 2017, respectively		
Additional paid-in capital	163,547	122,950
Accumulated other comprehensive loss	(56)	(102)
Accumulated deficit	(90,046)	(72,513)
TOTAL STOCKHOLDERS' EQUITY	73,447	50,337
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$79,713	$56,077

The accompanying notes are an integral part of these condensed consolidated financial statements.

Aeglea BioTherapeutics, Inc.

Condensed Consolidated Statements of Operations

(Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenues:				
Grant	$2,378	$1,479	$3,888	$2,462
Operating expenses:				
Research and development	$9,122	$5,835	$15,992	$10,784
General and administrative	2,926	2,364	5,811	4,729
Total operating expenses	12,048	8,199	21,803	15,513
Loss from operations	(9,670)	(6,720)	(17,915)	(13,051)
Other income (expense):				
Interest income	263	100	406	195
Other expense, net	(7)	(12)	(24)	(23)
Total other income	256	88	382	172
Net loss	$(9,414)	$(6,632)	$(17,533)	$(12,879)
Net loss per share, basic and diluted	$(0.46)	$(0.47)	$(0.94)	$(0.94)
Weighted-average common shares outstanding, basic and diluted	20,598,711	14,114,101	18,646,265	13,742,029

The accompanying notes are an integral part of these condensed consolidated financial statements.

Aeglea BioTherapeutics, Inc.

Condensed Consolidated Statements of Comprehensive Loss

(Unaudited)

(In thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net loss	$(9,414)	$(6,632)	$(17,533)	$(12,879)
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	42	8	46	(25)
Total comprehensive loss	$(9,372)	$(6,624)	$(17,487)	$(12,904)

The accompanying notes are an integral part of these condensed consolidated financial statements.

Aeglea BioTherapeutics, Inc.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(In thousands)

	Six Months Ended June 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(17,533)	$(12,879)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	145	114
Purchase net discount (premium) on marketable securities	401	(40)
Net (accretion of discount) amortization of premium on marketable securities	(107)	80
Stock-based compensation	1,831	1,066
Research and development services settled with stock	41	—
Other, net	(20)	(13)
Changes in operating assets and liabilities:		
Accounts receivable-grant	(1,203)	2
Prepaid expenses and other assets	(573)	29
Accounts payable	579	340
Deferred revenue	(20)	—
Accrued and other liabilities	(32)	(73)
Net cash used in operating activities	(16,491)	(11,374)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(118)	(317)
Purchases of marketable securities	(26,250)	(37,780)
Proceeds from maturities of marketable securities	11,870	17,010
Net cash used in investing activities	(14,498)	(21,087)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock in public offering, net of offering costs	37,690	11,551
Proceeds from employee stock plan purchases and stock option exercises	1,061	96
Net cash provided by financing activities	38,751	11,647
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	7,762	(20,814)
CASH AND CASH EQUIVALENTS		
Beginning of period	12,817	47,748
End of period	$20,579	$26,934

The accompanying notes are an integral part of these condensed consolidated financial statements.

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Aeglea BioTherapeutics, Inc.

Notes to Condensed Consolidated Financial Statements

1. The Company and Basis of Presentation

Aeglea BioTherapeutics, Inc. (“Aeglea” or the “Company”) is a clinical-stage biotechnology company that designs and develops innovative human enzyme therapeutics for patients with rare genetic diseases and cancer. The Company was formed as a Limited Liability Company (LLC) in Delaware on December 16, 2013 under the name Aeglea BioTherapeutics Holdings, LLC and was converted from a Delaware LLC to a Delaware corporation (the “LLC Conversion”) on March 10, 2015. The Company operates in one segment and has its principal offices in Austin, Texas.

Stock Offering

In April 2018, the Company issued and sold 5,046,510 shares of common stock in an underwritten public offering (“2018 Stock Offering”) pursuant to a shelf registration statement on Form S-3 at a public offering price of $8.00 per share, including 546,510 shares of common stock issued upon the partial exercise by the underwriters of their option to purchase additional shares. The net proceeds to the Company from this public offering were $37.7 million, after deducting underwriting discounts and commissions of $2.4 million and offering costs of $300,000. As of June 30, 2018, the Company had $36,000 in offering costs recorded as an outstanding liability on the balance sheet.

Liquidity

As of June 30, 2018, the Company had working capital of $72.7 million, an accumulated deficit of $90.0 million, and cash, cash equivalents, and marketable securities of $72.2 million. The Company has not generated any product revenues and has not achieved profitable operations. There is no assurance that profitable operations will ever be achieved, and, if achieved, could be sustained on a continuing basis. In addition, development activities, clinical and nonclinical testing, and commercialization of the Company’s products will require significant additional financing.

The Company is subject to a number of risks similar to other life science companies, including, but not limited to, risks related to the successful discovery and development of product candidates, raising additional capital, development of competing drugs and therapies, protection of proprietary technology and market acceptance of the Company’s products. As a result of these and other factors and the related uncertainties, there can be no assurance of the Company’s future success.

Based upon the Company’s current operating plans, the Company believes that it has sufficient resources to fund operations to the middle of 2020 with its existing cash, cash equivalents, and marketable securities. The Company will need to secure additional funding in the future, in order to carry out all of its planned research and development activities. If the Company is unable to obtain additional financing or generate license or product revenue, the lack of liquidity could have a material adverse effect on the Company’s future prospects.

Unaudited Interim Financial Information

The interim condensed consolidated financial statements included in this document are unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and reflect, in the

opinion of management, all adjustments of a normal and recurring nature that are necessary for a fair statement of the Company's financial position as of June 30, 2018, and its results of operations for the three and six months ended June 30, 2018 and 2017, and cash flows for the six months ended June 30, 2018 and 2017. The results of operations for the six months ended June 30, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018 or for any other future annual or interim period. The December 31, 2017 balance sheet was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States ("U.S. GAAP"). These financial statements should be read in conjunction with the audited financial statements included in the Company's Form 10-K for the year ended December 31, 2017 as filed with the SEC.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Such management estimates include those related to accruals of research and development related costs, stock-based compensation, and certain company income tax related items. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ significantly from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents consist of money market funds and debt securities and are stated at fair value.

Marketable Securities

All investments have been classified as available-for-sale and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its investments in debt securities at the time of purchase. The Company may or may not hold securities with stated maturities greater than one year until maturity. All available-for-sale securities are considered available to support current operations and are classified as current assets.

Unrealized gains and losses are excluded from earnings and are reported as a component of accumulated comprehensive loss. Realized gains and losses and declines in fair value judged to be other than temporary, if any, on available-for-sale securities are included in other income (expense). The cost of securities sold is based on the specific-identification method. There were no realized gains or losses on marketable securities for the six months ended June 30, 2018 and 2017. Interest on marketable securities is included in interest income.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents, and marketable securities. The Company’s investment policy limits investments to high credit quality securities issued by the U.S. government, U.S. government-sponsored agencies and highly rated banks, subject to certain concentration limits and restrictions on maturities. The Company’s cash, cash equivalents, and marketable securities are held by financial institutions in the United States that management believes are of high credit quality. Amounts on deposit may at times exceed federally insured limits. The Company has not experienced any losses on its deposits of cash and cash equivalents and its accounts are monitored by management to mitigate risk. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash and cash equivalents and bond issuers.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the assets. Repairs and maintenance that do not extend the life or improve an asset are expensed as incurred. Upon retirement or sale, the cost of disposed assets and their related accumulated depreciation and amortization are removed from the balance sheet. Any gain or loss is credited or charged to operations.

The useful lives of the property and equipment are as follows:

Laboratory equipment	5 years
Furniture and office equipment	5 years
Computer equipment	3 years
Software	3 years
Leasehold improvements	Shorter of remaining lease term or estimated useful life

Impairment of Long-Lived Assets

Long-lived assets are reviewed for indications of possible impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amounts to the future undiscounted cash flows attributable to these assets. An impairment loss is recognized to the extent an asset group is not recoverable, and the carrying amount exceeds the projected discounted future cash flows arising from these assets. There were no impairments of long-lived assets for the six months ended June 30, 2018 and 2017.

Accrued Research and Development Costs

The Company records the costs associated with research nonclinical studies, clinical trials, and manufacturing development as incurred. These costs are a significant component of the Company's research and development expenses, with a substantial portion of the Company's on-going research and development activities conducted by third-party service providers, including contract research and manufacturing organizations.

The Company accrues for expenses resulting from obligations under agreements with contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), and other outside service providers for which payment flows do not match the periods over which materials or services are provided to the Company. Accruals are recorded based on estimates of services received and efforts expended pursuant to agreements established with CROs, CMOs, and other outside service providers. These estimates are typically based on contracted amounts applied to the proportion of work performed and determined through analysis with internal personnel and external service providers as to the progress or stage of completion of the services. The Company makes significant judgments and estimates in determining the accrual balance in each reporting period. In the event advance payments are made to a CRO, CMO, or outside service provider, the payments will be recorded as a prepaid asset which will be amortized as the contracted services are performed. As actual costs become known, the Company adjusts its accruals. Inputs, such as the services performed, the number of patients enrolled, or the study duration, may vary from the Company's estimates, resulting in adjustments to research and development expense in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect the Company's results of operations. The Company has not experienced any material deviations between accrued and actual research and development expenses.

Leases

The Company entered into lease agreements for its office and laboratory facilities. The leases are classified as operating leases. The Company records rent expense on a straight-line basis over the term of the leases and, accordingly records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability. Incentives granted under the Company's facilities leases, including allowances to fund leasehold improvements, are deferred and are recognized as adjustments to rental expense on a straight-line basis over the term of the lease.

Fair Value of Financial Instruments

The Company uses fair value measurements to record fair value adjustments to certain financial and non-financial assets and liabilities and to determine fair value disclosures. The accounting standards define fair value, establish a framework for measuring fair value, and require disclosures about fair value measurements. Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required to be recorded at fair value, the principal or most advantageous market in which the Company would transact are considered along with assumptions that market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions, and risk of nonperformance.

The accounting standard for fair value establishes a fair value hierarchy based on three levels of inputs, the first two of which are considered observable and the last unobservable, that requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. A financial instrument's categorization within the fair value hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The three levels of inputs that may be used to measure fair value are as follows:

Level 1: Observable inputs, such as quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3: Valuations based on unobservable inputs to the valuation methodology and including data about assumptions that market participants would use in pricing the asset or liability based on the best information available under the circumstances.

Financial instruments carried at fair value include cash, cash equivalents, and marketable securities. The carrying amount of accounts receivable, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities.

Revenue Recognition

The Company's sole source of revenue is grant revenue related to a $19.8 million research grant received from the Cancer Prevention and Research Institute of Texas ("CPRIT"), covering a four-year period from June 1, 2014 through May 31, 2018. Grant revenue is recognized when qualifying costs are incurred and there is reasonable assurance that the conditions of the award have been met for collection. Proceeds received prior to the costs being incurred or the conditions of the award being met are recognized as deferred revenue until the services are performed and the conditions of the award are met (see Note 5).

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs include, but are not limited to, salaries, benefits, travel, stock-based compensation, consulting costs, contract research service costs, laboratory supplies and facilities, contract manufacturing costs, and costs paid to other third parties that conduct research and development activities on the Company's behalf. Amounts incurred in connection with license agreements are also included in research and development expense.

Certain research and development costs incurred were settled contractually by the Company issuing a variable number of the Company's shares determined by dividing the fixed monetary amount of costs incurred by the issuance-date fair value of the issuable shares. The Company recorded research and development expense for these costs and accrued for the fixed monetary amount as an accrued liability as the services were rendered until the amount was settled. In June 2015, the remaining Company obligation to settle these costs with Company shares was converted to a cash-based payment through a contract amendment with the service provider.

Advance payments for goods or services to be rendered in the future for use in research and development activities are recorded as a prepaid asset and expensed as the related goods are delivered or the services are performed.

Stock-Based Compensation

The Company recognizes the cost of stock-based awards granted to employees based on the estimated grant-date fair values of the awards. The value of the award is recognized as compensation expense on a straight-line basis over the requisite service period. Forfeitures are recognized when they occur, which may result in the reversal of compensation costs in subsequent periods as the forfeitures arise. The Company recognizes the cost of stock-based awards granted to nonemployees at their then-current fair values as services are performed, and are remeasured through the counterparty performance date.

Income Taxes

The Company and its seven wholly-owned subsidiary corporations use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the financial statements and the tax bases of assets and liabilities. Additionally, any changes in income tax laws are immediately recognized in the year of enactment.

A valuation allowance is established against the deferred tax assets to reduce their carrying value to an amount that is more likely than not to be realized. The deferred tax assets and liabilities are classified as noncurrent along with the related valuation allowance. Due to a lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance.

The Company recognizes benefits of uncertain tax positions if it is more likely than not that such positions will be sustained upon examination based solely on the technical merits, as the largest amount of benefits that is more likely than not to be realized upon the ultimate settlement. The Company's policy is to recognize interest and penalties related to the unrecognized tax benefits as a component of income tax expense.

Comprehensive Loss

Comprehensive loss is the change in stockholders' equity from transactions and other events and circumstances other than those resulting from investments by stockholders and distributions to stockholders. The Company's other comprehensive income (loss) is currently comprised of changes in unrealized gains and losses on available-for-sale securities.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which establishes a comprehensive new lease accounting model. The new standard: (a) clarifies the definition of a lease; (b) requires a dual approach to lease classification similar to current lease classifications; and, (c) causes lessees to recognize leases on the balance sheet as a lease liability with a corresponding right-of-use asset for leases with a lease-term of more than twelve months. The new standard is effective for fiscal years and interim periods beginning after December 15, 2018 and requires modified retrospective application. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-02 will have on its consolidated financial statements, but expect the impact to be limited to the operating lease agreements for the office and laboratory spaces in Austin, Texas.

In June 2018, the FASB issued ASU No. 2018-07, Compensation – Stock Compensation (Topic 718), which expanded the scope of Topic 718 to include share-based transactions for acquiring goods and services from nonemployees. The amendment specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. Consistent with the accounting requirement for employee share-based payment awards, nonemployee share-based payment awards within the scope of 718 are measured at grant-date fair value of the equity instruments that an entity is obligated to issue when the good has been delivered or the service has been rendered and any other conditions necessary to earn the right to benefit from the instruments have been satisfied. The amendment is effective for fiscal years beginning after December 15, 2019 and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted. The Company does not expect the adoption of ASU 2018-07 to have a material impact on its consolidated financial statements.

3. Cash Equivalents and Marketable Securities

The following tables summarize the estimated fair value of the Company's cash equivalents and marketable securities and the gross unrealized gains and losses (in thousands):

	June 30, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash equivalents:				
Money market funds	$6,807	$ —	$ —	$ 6,807
Reverse repurchase agreements	6,250	—	—	6,250
Commercial paper	5,990			