REPLIGEN CORP Form 10-Q November 05, 2015 Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

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 000-14656

REPLIGEN CORPORATION

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of

04-2729386 (I.R.S. Employer

incorporation or organization)

Identification No.)

41 Seyon Street, Bldg. 1, Suite 100

Waltham, MA (Address of principal executive offices)

02453 (Zip Code)

Registrant s telephone number, including area code: (781) 250-0111

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 website, 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 x No "

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. (Check one):

Large accelerated filer x

Accelerated filer

Non-accelerated filer " (Do not check if a smaller reporting company) Smaller reporting company " Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.): Yes " No x

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of October 29, 2015.

Class
Common Stock, par value \$.01 per share

Number of Shares 32,943,553

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REPLIGEN CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except share and per share data)	September 30, 2015		December 31, 2014	
Assets				
Current assets:				
Cash and cash equivalents	\$	48,084	\$	35,363
Marketable securities		20,790		23,090
Accounts receivable, less reserve for doubtful accounts of \$52 and \$41,				
respectively		10,321		7,760
Other receivables		57		240
Inventories		15,899		12,384
Deferred tax asset, net		5		5
Prepaid expenses and other current assets		1,123		2,104
Total current assets		96,279		80,946
		,		•
Property, plant and equipment, at cost:				
Leasehold improvements		13,258		9,108
Equipment		13,513		13,116
Furniture and fixtures		2,722		2,270
Construction in progress		228		3,848
				,
Total property, plant and equipment, at cost		29,721		28,342
Less: Accumulated depreciation		(15,748)		(13,816)
•				, , ,
Property, plant and equipment, net		13,973		14,526
Long-term marketable securities		1,651		3,550
Intangible assets, net		13,154		14,636
Goodwill		14,346		14,185
Restricted cash		450		450
Total assets	\$	139,853	\$	128,293
	·	,	·	,
Liabilities and stockholders equity				
Current liabilities:				
Accounts payable	\$	2,951	\$	3,863
Accrued liabilities		12,758		6,819
		,		,
Total current liabilities		15,709		10,682
Other long-term liabilities		2,693		5,879
Commitments and contingencies (Note 11)		_,0,0		2,0.7
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Stockholders equity:		
Preferred stock, \$.01 par value, 5,000,000 shares authorized, no shares issued		
or outstanding		
Common stock, \$.01 par value, 80,000,000 shares authorized, 32,943,553		
shares at September 30, 2015 and 32,774,374 shares at December 31, 2014		
issued and outstanding	329	328
Additional paid-in capital	201,657	198,064
Accumulated other comprehensive income (loss)	(8,728)	(5,773)
Accumulated deficit	(71,807)	(80,887)
Total stockholders equity	121,451	111,732
Total liabilities and stockholders equity	\$ 139,853	\$ 128,293

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

REPLIGEN CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(Unaudited)

,	2015		2014		2015		2014
\$	19,814	\$		\$	62,088	\$	45,038
			126				2,117
	19,814		15,278		62,088		47,155
	8,444		6,931		25,103		19,938
	1,490		1,650		4,309		4,281
	5,959		4,471		18,226		12,180
	233		10		2,114		126
	16,126		13,062		49,752		36,525
	3,688		2,216		12,336		10,630
	37		64		92		250
	(8)		(12)		(24)		(38)
	(38)		(14)		(175)		54
	3,679		2,254		12,229		10,896
	1,141		788		3,149		2,327
\$	2,538	\$	1,466	\$	9,080	\$	8,569
\$	0.08	\$	0.04	\$	0.28	\$	0.27
\$	0.08	\$	0.04	\$	0.27	\$	0.26
32	2,925,004		32,677,003	3	32,860,382	3	2,292,588
33	3,689,560		33,327,377	3	33,617,999	3	3,099,599
	65		34		43		46
	\$ \$ \$ \$	\$ 19,814 19,814 8,444 1,490 5,959 233 16,126 3,688 37 (8) (38) 3,679 1,141 \$ 2,538 \$ 0.08 \$ 0.08	\$ 19,814 \$ 19,814 \$ 19,814 \$ 19,814 \$ 1,490 \$ 5,959 \$ 233 \$ 16,126 \$ 3,688 \$ 37 \$ (8) \$ (38) \$ 3,679 \$ 1,141 \$ \$ 2,538 \$ \$ \$ 0.08 \$ \$ \$ 0.08 \$ \$ \$ 0.08 \$ \$	2015 2014 \$ 19,814 \$ 15,152 19,814 15,278 8,444 6,931 1,490 1,650 5,959 4,471 233 10 16,126 13,062 3,688 2,216 37 64 (8) (12) (38) (14) 3,679 2,254 1,141 788 \$ 2,538 \$ 1,466 \$ 0.08 \$ 0.04 \$ 0.08 \$ 0.04 32,925,004 32,677,003 33,689,560 33,327,377	\$ 19,814 \$ 15,152 \$ 126 19,814 15,278 8,444 6,931 1,490 1,650 5,959 4,471 233 10 16,126 13,062 3,688 2,216 37 64 (8) (12) (38) (14) 3,679 2,254 1,141 788 \$ 2,538 \$ 1,466 \$ \$ 0.08 \$ 0.04 \$ \$ 0.08 \$ 0.04 \$ \$ 32,925,004 32,677,003 33 33,689,560 33,327,377 33	2015 2014 2015 \$ 19,814 \$ 15,152 \$ 62,088 126 \$ 19,814 \$ 15,278 \$ 62,088 125,103 \$ 8,444 \$ 6,931 \$ 25,103 1,490 \$ 1,650 \$ 4,309 5,959 4,471 18,226 \$ 233 \$ 10 \$ 2,114 16,126 13,062 49,752 12,336 37 64 92 (24) (24) (38) (12) (24) (24) (38) (14) (175) \$ 3,688 \$ 2,216 \$ 12,336 37 64 92 (24) (24) (38) (14) (175) (175) (24) (38) (14) (175) (24) (38)	\$ 19,814 \$ 15,152 \$ 62,088 \$ 126 19,814 15,278 62,088 8,444 6,931 25,103 1,490 1,650 4,309 5,959 4,471 18,226 233 10 2,114 16,126 13,062 49,752 3,688 2,216 12,336 37 64 92 (8) (12) (24) (38) (14) (175) 3,679 2,254 12,229 1,141 788 3,149 \$ 2,538 \$ 1,466 \$ 9,080 \$ \$ 0.08 \$ 0.04 \$ 0.28 \$ \$ 0.08 \$ 0.04 \$ 0.27 \$ 32,925,004 32,677,003 32,860,382 3 33,689,560 33,327,377 33,617,999 3

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Foreign currency translation loss	(596)	(3,157)	(2,998)	(4,763)
Comprehensive income (loss)	\$ 2,007	\$ (1,657)	\$ 6,125	\$ 3,852

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

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REPLIGEN CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)	Nine	months ende	ed September 2014	30,
Cash flows from operating activities:				
Net income:	\$	9,080	\$ 8,56	59
Adjustments to reconcile net income to net cash provided by operating activities:				
Depreciation and amortization		3,449	2,96	55
Stock-based compensation expense		2,668	1,38	36
Deferred tax expense		218	26	51
Loss on revaluation of contingent consideration		2,114	12	26
Loss on disposal of assets		1		3
Bad debt reserve		11		
Changes in assets and liabilities:				
Accounts receivable		(2,767)	(76	53)
Other receivables		183	6,67	78
Inventories		(4,051)	(1,34	1 7)
Prepaid expenses and other current assets		699	8	38
Accounts payable		(749)	92	21
Accrued liabilities		1,085	(1,98	34)
Long-term liabilities		(240)	(25	55)
Net cash provided by operating activities		11,701	16,64	18
Cash flows from investing activities:				
Purchases of marketable securities		(14,090)	(24,23	
Redemptions of marketable securities		18,264	30,11	
Acquisition of assets of Refine Technology, LLC			(21,23	
Increase in restricted cash			(25	
Purchases of property, plant and equipment		(2,055)	(2,96	54)
Net cash provided by (used in) investing activities		2,119	(18,56	59)
Cash flows from financing activities:		·	·	
Exercise of stock options		927	1,48	
Payment of contingent considerations		(99)	(60)4)
Net cash provided by financing activities		828	88	32
Effect of exchange rate changes on cash and cash equivalents		(1,927)	(2,88	34)
Net increase (decrease) in cash and cash equivalents		12,721	(3,92	23)

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Cash and cash equivalents, beginning of period	35,363	39,830
Cash and cash equivalents, end of period	\$ 48,084	\$ 35,907
Supplemental disclosure of non-cash investing activities:		
Income taxes paid	\$ 2,671	\$ 671

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

REPLIGEN CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Basis of Presentation

The consolidated financial statements included herein have been prepared by Repligen Corporation (the Company, Repligen or we) in accordance with generally accepted accounting principles in the United States (U.S. GAAP) and pursuant to the rules and regulations of the Securities and Exchange Commission (SEC), for Quarterly Reports on Form 10-Q and Article 10 of Regulation S-X and do not include all of the information and footnote disclosures required by U.S. GAAP. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and accompanying notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2014.

In the opinion of management, the accompanying unaudited consolidated financial statements include all adjustments, consisting of only normal, recurring adjustments necessary for a fair presentation of the financial position, results of operations and cash flows. The results of operations for the interim periods presented are not necessarily indicative of results to be expected for the entire year.

The preparation of 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 disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Recently Issued Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, which amends the guidance for accounting for revenue from contracts with customers. This ASU supersedes the revenue recognition requirements in Accounting Standards Codification Topic 605, *Revenue Recognition*, and creates a new Topic 606, *Revenue from Contracts with Customers*. This guidance is effective for fiscal years beginning after December 15, 2017, with early adoption permitted in fiscal years beginning after December 15, 2016. Two adoption methods are permitted: retrospectively to all prior reporting periods presented, with certain practical expedients permitted; or retrospectively with the cumulative effect of initially adopting the ASU recognized at the date of initial application. The Company has not yet determined which adoption method it will utilize or the effect that the adoption of this guidance will have on its consolidated financial statements.

In July 2015, the FASB issued ASU 2015-11, Simplifying the Measurement of Inventory, (ASU 2015-11). ASU 2015-11 requires inventory be measured at the lower of cost and net realizable value and options that currently exist for market value be eliminated. ASU 2015-11 defines net realizable value as estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance is effective prospectively for reporting periods beginning after December 15, 2016 and interim periods within those fiscal years with early adoption permitted. The Company does not expect the adoption of ASU 2015-11 to have a material impact on its consolidated financial statements.

2. Acquisitions, Goodwill and Other Intangible Assets

Acquisition of Refine Technology, LLC

On June 2, 2014, pursuant to the terms of the Asset Purchase Agreement, dated as of June 2, 2014 (the Asset Purchase Agreement), by and among the Company, Refine Technology, LLC (a limited liability company formed under the laws of the State of New Jersey) (Refine), the members of Refine, Jerry Shevitz, Refine Technology Sales LLC (a limited liability company formed under the laws of the State of New Jersey) and Refine Technology Sales Asia PTE. LTD. (a limited private company organized in the Republic of Singapore), the Company acquired the business of Refine, including Refine s Alternating Tangential Flow (ATF) System, a market-leading device used to significantly increase product yield during the fermentation step of the biologic drug manufacturing process (the Refine Business and the acquisition of the Refine Business, the Refine Acquisition). Pursuant to the Asset Purchase Agreement, Repligen purchased all of the assets related to Refine s ATF system and assumed certain specified liabilities related to Refine s ATF system. This acquisition strengthened Repligen s bioprocessing business by adding a complementary product line while expanding its direct sales presence worldwide. The transaction was accounted for as a purchase of a business under Accounting Standards Codification (ASC) 805, Business Combinations. The terms of the acquisition included an upfront cash payment of \$21,236,000 less \$66,000 as a result of the final determination of working capital, issuance of 215,285 shares of the Company s \$0.01 par value common stock valued at \$4,000,000, potential milestone payments totaling up to \$10,900,000 for the achievement of specific sales targets in the years 2014, 2015 and 2016, and future potential payments up to \$7,500,000 out of any amounts that might be received in connection with the resolution, withdrawal or settlement of certain patent disputes with a third party. During the nine months ended September 30, 2015, the Company paid Refine a \$1,000,000 milestone payment for achievement of the 2014 sales

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target under the Asset Purchase Agreement. The \$10,900,000 contingent consideration had an initial probability weighted fair value at acquisition of \$1,370,000. The \$7,500,000 contingent consideration had only a nominal probability weighted fair value at acquisition. In addition to the initial consideration, approximately \$774,000 was paid to Refine following the acquisition under a Transition Services Agreement under which certain employees of Refine provided services to the Company for up to six months in support of the Refine Business. As these payments were contingent upon future service, they were recognized ratably as operating expense while the services were provided.

Consideration Transferred

The Company accounted for the Refine Acquisition as the purchase of a business under U.S. GAAP. Under the acquisition method of accounting, the assets of the Refine Business were recorded as of the acquisition date, at their respective fair values, and consolidated with those of Repligen. The fair value of the net assets acquired was approximately \$26,540,000.

The preparation of the valuation required the use of significant assumptions and estimates. Critical estimates included, but were not limited to, future expected cash flows, including projected revenues and expenses, and the applicable discount rates. These estimates were based on assumptions that the Company believes to be reasonable. However, actual results may differ from these estimates.

The total consideration transferred follows (in thousands):

Cash consideration,	\$21,170
Value of common stock issued	4,000
Estimated fair value of contingent consideration	1,370
-	
Total consideration transferred	\$ 26,540

The fair value of contingent consideration was determined based upon a probability weighted analysis of expected future payments to be made to Refine. The Company paid to Refine \$1,000,000 during the nine months ended September 30, 2015 for achievements of sales targets met in 2014, and could make payments of up to \$9,900,000 if specific sales targets are met for years 2015 and 2016. In addition, the Company could pay Refine up to \$7,500,000 out of any receipts that might be received in connection with the resolution, withdrawal or settlement of certain patent disputes with a third party. The liability for contingent consideration is included in current and long-term liabilities on the consolidated balance sheets and will be remeasured at each reporting period until the contingency is resolved. Please see Note 8 Fair Value Measurement for further details.

Acquisition related costs are not included as a component of consideration transferred, but are expensed in the periods in which the costs are incurred. The Company incurred approximately \$818,000 in transaction costs related to the Refine Acquisition. The transaction costs are included in 2014 selling, general and administrative expenses in the consolidated statements of comprehensive income.

Fair Value of Net Assets Acquired

The allocation of purchase price was based on the fair value of assets acquired and liabilities assumed as of June 2, 2014. The components and allocation of the purchase price consists of the following amounts (in thousands):

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\$ 1,647
1,003
184
85
6,400
2,000
1,600
700
(431)
13,352
\$ 26,540

Of the consideration paid, \$6,400,000 represents the fair value of customer relationships that will be amortized over the determined useful life of 10 years, and \$2,000,000 represents the fair value of developed technology that will be amortized over a determined useful life of 15 years. \$700,000 represents the fair value of trademark and trade name determined to have an indefinite useful life and is not subject to amortization.

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\$1,600,000 of the consideration paid represents the fair value of acquired IPR&D projects that are considered identifiable assets as of the acquisition date. Those assets are considered indefinite lived until efforts associated with the projects are completed or abandoned. The major acquired technology IPR&D relates to the development of a single use system product extension to the ATF system business. The IPR&D project assets are not currently amortized and are reviewed for impairment at least annually. There was no evidence of impairment to IPR&D as of September 30, 2015. The excess of the purchase price over the fair value of tangible and intangible assets acquired was recorded to goodwill. The goodwill recognized is attributable to expected synergies that the Company will realize from this acquisition. This goodwill is deductible for tax purposes over 15 years from the date of acquisition.

Revenue, Net Income and Pro Forma Presentation

The Company recorded revenue from Refine of \$466,000 from June 2, 2014 through June 30, 2014. For the three months ended September 30, 2015 and 2014, the Company recorded revenue of approximately \$3.8 million and \$2.2 million, respectively. For the nine months ended September 30, 2015 and 2014, the Company recorded revenue of approximately \$9.2 million and \$2.6 million, respectively. The Company has included the operating results of Refine in its consolidated statements of operations since the June 2, 2014 acquisition date. The following table presents unaudited supplemental pro forma information for the three- and nine-month periods ended September 30, 2014, as if the Refine Acquisition had occurred as of January 1, 2013.

	(in thousands, except per share amounts Three months ended					
	Sep	tember 30,	Nine m	onths ended		
		2014	Septem	ber 30, 2014		
Total revenue	\$	15,278	\$	50,937		
Net income		1,848		9,890		
Earnings per share:						
Basic	\$	0.04	\$	0.29		
Diluted	\$	0.04	\$	0.28		

The unaudited pro forma information for the three- and nine-month periods ended September 30, 2015 and 2014 was calculated after applying the Company s accounting policies and the impact of acquisition date fair value adjustments.

Other Intangible Assets

Intangible assets, except for the Refine Technology, LLC tradename and in-process research and development, are amortized over their useful lives using the estimated economic benefit method, as applicable, and the amortization expense is recorded within selling, general and administrative expense in the Company s statements of comprehensive income. The Refine Technology, LLC tradename and in-process research and development are not amortized. The Company reviews its indefinite-lived intangible assets not subject to amortization to determine if adverse conditions exist or a change in circumstances exists that would indicate an impairment. Intangible assets and their related useful lives are reviewed at least annually to determine if any adverse conditions exist that would indicate the carrying value of these assets may not be recoverable. More frequent impairment assessments are conducted if certain conditions exist, including a change in the Company s competitive landscape, any internal decisions to pursue new or different technology strategies, a loss of a significant customer, or a significant change in the marketplace, including changes in the prices paid for its products or changes in the size of the market for its products. An impairment results if the carrying value of the asset exceeds the estimated fair value of the asset. If the estimate of an intangible asset s remaining useful life is changed, the remaining carrying amount of the intangible asset is amortized prospectively over

the revised remaining useful life. The Company continues to believe that its intangible assets are recoverable at September 30, 2015.

Other intangible assets consisted of the following at September 30, 2015:

(In thousands)	s Carrying mount	 ımulated ortization	Weighted Average Useful Life (in years)
Technology developed	\$ 3,295	\$ (953)	12
In process research and development	1,600		
Patents	240	(170)	8
Customer relationships	11,804	(3,362)	9
Trademark/ tradename	700		
Total other intangible assets	\$ 17,639	\$ (4,485)	10

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Other intangible assets consisted of the following at December 31, 2014:

(In thousands)	Carrying mount	 umulated ortization	Weighted Average Useful Life (in years)
Technology developed	\$ 3,338	\$ (750)	12
In process research and development	1,600		
Patents	240	(148)	8
Customer relationships	12,202	(2,546)	9
Trademark/ tradename	700		
Total other intangible assets	\$ 18,080	\$ (3,444)	10

Amortization expense for amortized intangible assets was approximately \$1,201,000 for the nine-month period ended September 30, 2015. In each of the next five years, the Company expects to record amortization expense (in thousands) of:

Years Ending	Amortiza	tion Expense
December 31, 2015 (three months remaining)	\$	443
December 31, 2016		1,703
December 31, 2017		1,703
December 31, 2018		1,539
December 31, 2019		1,524
December 31, 2020		1,202

3. Revenue Recognition

Product Sales

The Company s revenue recognition policy is to recognize revenues from product sales and services in accordance with ASC 605, *Revenue Recognition*. These standards require that revenues are recognized when persuasive evidence of an arrangement exists, product delivery, including customer acceptance, has occurred or services have been rendered, the price is fixed or determinable and collectability is reasonably assured. Determination of whether these criteria have been met are based on management s judgments primarily regarding the fixed nature of the fee charged for the product delivered and the collectability of those fees. The Company has a few longstanding customers who comprise the majority of revenue and have excellent payment histories and therefore the Company does not require collateral. The Company has had no significant write-offs of uncollectible invoices in the periods presented. When more than one element such as equipment, consumables, and services are contained in a single arrangement, the Company allocates revenue among the elements based on each element s relative selling price, provided that each element meets the criteria for treatment as a separate unit of accounting. An item is considered a separate unit of accounting if it has value to the customer on a stand-alone basis. The selling price of the undelivered elements is determined by the price charged when the element is sold separately, or in cases when the item is not sold separately, by third-party evidence of selling price or management s best estimate of selling price.

The Company s product revenues are from the sale of bioprocessing products, equipment devices, and related consumables used with these equipment devices to customers in the life science and biopharmaceutical industries. For product sales to end customers, revenue is recognized, net of discounts, when both the title and risk of loss have transferred to the customer, as determined by the shipping terms, provided there are no uncertainties regarding acceptance, and all obligations have been completed. Generally, the Company s product arrangements for equipment sales are multiple element arrangements, and may include services, such as installation and training, and multiple products, such as consumables and spare parts. In accordance with ASC 605-25, based on the terms and conditions of the product arrangements, the Company believes that these services and undelivered products can be accounted for separately from the delivered product element, as the delivered products have value to the Company s customers on a stand-alone basis. Accordingly, revenue for services not yet performed at the time of product shipment are deferred and recognized as such services are performed. The relative selling price of any undelivered products is also deferred at the time of shipment and recognized as revenue when these products are delivered. For product sales to distributors, the Company recognizes revenue for both equipment and consumables upon delivery to the distributor unless direct shipment to the end user is requested. In this case, revenue is recognized upon delivery to the end user s location. In general, distributors are responsible for shipment to the end customer along with installation, training and acceptance of the equipment by the end customer. Sales to distributors are not contingent upon resale of the product.

At the time of sale, the Company also evaluates the need to accrue for warranty and sales returns. The supply agreements the Company has with its customers and the related purchase orders identify the terms and conditions of each sale and the price of the goods ordered. Due to the nature of the sales arrangements, inventory produced for sale is tested for quality specifications prior to shipment. Since the product is manufactured to order and in compliance with required specifications prior to shipment, the likelihood of sales returns, warranty or other issues is largely diminished. Furthermore, there is no customer right of return in the Company s sales agreements. Sales returns and warranty issues are infrequent and have had nominal impact on the Company s financial statements historically.

Therapeutics Licensing Agreements

Activities under licensing agreements are evaluated in accordance with ASC 605-25 to determine if they represent a multiple element revenue arrangement. The Company identifies the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting. The Company accounts for those components as separate units of accounting if the following two criteria are met:

The delivered item or items have value to the customer on a stand-alone basis.

If there is a general right of return relative to the delivered items, delivery or performance of the undelivered items is considered probable and within the Company s control.

Factors considered in this determination include, among other things, whether any other vendors sell the items separately and if the licensee could use the delivered item for its intended purpose without the receipt of the remaining deliverables. If multiple deliverables included in an arrangement are separable into different units of accounting, the Company allocates the arrangement consideration to those units of accounting. The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable. Arrangement consideration is allocated at the inception of the arrangement to the identified units of accounting based on their relative selling price. Revenue is recognized for each unit of accounting when the appropriate revenue recognition criteria are met.

Future milestone payments, if any, under a license agreement will be recognized under the provisions of ASC 605-28, which the Company adopted on January 1, 2011. The Company has elected to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. A milestone is substantive if:

It can only be achieved based in whole or in part on either the Company s performance or the occurrence of a specific outcome resulting from the Company s performance;

There is substantive uncertainty at the date an arrangement is entered into that the event will be achieved; and

It would result in additional payments being due to the entity.

The commercial milestone payments and royalty payments received under license agreements, if any, will be recognized as revenue when they are earned.

Sale of Intellectual Property to BioMarin

In January 2014, the Company entered into an asset purchase agreement (the BioMarin Asset Purchase Agreement) with BioMarin Pharmaceutical Inc. (BioMarin) to sell the Company s histone deacetylase inhibitor (HDACi) portfolio. Pursuant to the terms of the BioMarin Asset Purchase Agreement, the Company received \$2 million from BioMarin as an upfront payment on January 30, 2014 and a payment of approximately \$126,000 on September 3, 2014 upon completion of the Technology Transfer. The Company is entitled to receive up to \$160 million in potential future milestone payments for the development, regulatory approval and commercial sale of portfolio compounds included in the agreement. These potential milestone payments are approximately 37% related to clinical development and 63% related to initial commercial sales in specific geographies. In addition, the Company is eligible to receive royalties on sales of therapeutic products originating from the HDACi portfolio. The royalty rates are tiered and begin in the mid-single-digits for the first HDACi portfolio product and for the first non-HDACi portfolio product with lesser amounts for any backup products developed under the BioMarin Asset Purchase Agreement. The Company s receipt of these royalties is subject to customary offsets and deductions. There are no refund provisions in this agreement. The Company recognized \$2.1 million of revenue in the nine-month period ended September 30, 2014, related to the transfer of the HDACi technology under the BioMarin Asset Purchase Agreement. The Company did not recognize any revenue in the three- and nine-month periods ended September 30, 2015. Any milestones earned upon specified clinical development or commercial sales events or future royalty payments under the BioMarin Asset Purchase Agreement will be recognized as revenue when they are earned.

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Activities under this agreement were evaluated in accordance with ASC 605-25 to determine if they represented a multiple element revenue arrangement. The Company identified the following deliverables in the BioMarin Asset Purchase Agreement:

The assignment by the Company to BioMarin of the Repligen Technology (Repligen Know-How and Repligen Patents) and the Scripps Agreement (the Transferred Assets);

The transfer of certain notebooks, data, documents, biological materials (if any) and other such documents in the Company s possession that might be useful to further development of the program (the Technology Transfer).

Two criteria must be met in order for a deliverable to be considered a separate unit of accounting. The first criterion requires that the delivered item or items have value to the customer on a stand-alone basis. The second criterion, which relates to evaluating a general right of return, is not applicable because such a provision does not exist in the BioMarin Asset Purchase Agreement. The deliverables outlined above were deemed to have stand-alone value and to meet the criteria to be accounted for as separate units of accounting. Factors considered in this determination included, among other things, BioMarin s right under the agreement to assign the Transferred Assets, whether any other vendors sell the items separately and if BioMarin could use the delivered item for its intended purpose without the receipt of the remaining deliverables. If multiple deliverables included in an arrangement are separable into different units of accounting, the multiple-element arrangements guidance addresses how to allocate the arrangement consideration to those units of accounting. The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable. Arrangement consideration is allocated at the inception of the arrangement to the identified units of accounting based on their relative selling price.

The Company identified the arrangement consideration to allocate among the units of accounting as the \$2.0 million non-refundable up-front payment and the \$126,000 payment to be received upon completion of the Technology Transfer. The Company excluded the potential milestone payments provided for in the BioMarin Asset Purchase Agreement from the arrangement consideration, as they were not considered fixed or determinable at the time the BioMarin Asset Purchase Agreement was signed. Because the Company had not sold these items on a stand-alone basis previously, it had no vendor-specific objective evidence of selling price. Furthermore, the Company did not have detailed third-party evidence of selling price, and as a result the Company used its best estimate of selling price for each item. In determining these prices, the Company considered what it would be willing to sell the items for on a stand-alone basis, what the market would bear for such items and what another party might charge for these items.

The up-front arrangement consideration allocated to the Transferred Assets was recognized upon execution of the BioMarin Asset Purchase Agreement as the risks and rewards associated with the Transferred Assets transferred at that time. The Company used a discounted cash flow analysis to determine the value of the Transferred Assets. Key assumptions in the analysis included: the estimated market size for a compound targeted at Friedreich's Ataxia, the estimated remaining costs of development and time to commercialization, and the probability of successfully developing and commercializing the program. Based on this analysis, the Company allocated \$2,115,000 to the value of the Transferred Assets. However, as the recognized revenue is limited to the non-contingent consideration received, the Company recognized approximately \$2,000,000, the amount of the up-front payment, as revenue in the first quarter of 2014.

The estimated selling price of the Technology Transfer items was approximately \$300,000, resulting in consideration allocation of approximately \$11,000. However, as this item was not delivered prior to March 31, 2014, the Company

did not recognize any revenue related to the Technology Transfer in the three months ended March 31, 2014. The Company received the payment and recognized \$126,000 of other revenues in September 2014 upon the completion of the Technology Transfer. The Company believes that a change in the key assumptions used to determine best estimate of selling price for each of the deliverables would not have a significant effect on the allocation of arrangement consideration.

In addition to the \$2.1 million up-front payment, the Company is also eligible to receive up to \$160 million in potential milestone payments from BioMarin comprised of:

Up to \$60 million related to the achievement of specified clinical and regulatory milestone events; and

Up to \$100 million related to the achievement of specified commercial sales events, specifically the first commercial sale in specific territories.

The Company evaluated the potential milestones in accordance with ASC 605-28, which allows an entity to make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. This evaluation included an assessment of the risks that must be overcome to achieve the respective milestone as well as whether the achievement of the milestone was due in part to the Company s initial clinical work, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement. There is considerable judgment involved in determining whether a milestone satisfies all of the criteria required to conclude that a milestone is substantive. Milestones that are not considered substantive are recognized as earned if there are no remaining performance obligations or over the remaining period of performance, assuming all other revenue recognition criteria are met.

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The Company believes that the \$60 million of specified clinical and regulatory milestone payments are substantive. Therefore, any such milestones achieved will be recognized as revenue when earned.

Any milestones achieved upon specified commercial sales events or future royalty payments are considered contingent revenue under the BioMarin Asset Purchase Agreement, and will be recognized as revenue when they are earned as there are no undelivered elements remaining and no continuing performance obligations under the arrangement.

4. Accumulated Other Comprehensive Income

The following table summarizes the changes in accumulated other comprehensive income by component:

(In thousands)	(los	ized gain ss) on tments	tra	gn currency Inslation gain (loss)	Total
Balance at December 31, 2014	\$	(33)	\$	(5,740)	\$ (5,773)
Other comprehensive income/(loss) before reclassifications Amounts reclassified from accumulated other comprehensive income		43		(2,998)	(2,955)
Net current period other comprehensive income/(loss)	ф	43	ф	(2,998)	(2,955)
Balance at September 30, 2015	\$	10	\$	(8,738)	\$ (8,728)

5. Earnings Per Share

The Company reports earnings per share in accordance with Accounting Standards Codification Topic 260, *Earnings Per Share*, which establishes standards for computing and presenting earnings per share. Basic earnings per share is computed by dividing net income available to common shareholders by the weighted-average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing net income available to common shareholders by the weighted-average number of common shares and dilutive common share equivalents then outstanding. Potential common share equivalents consist of restricted stock awards and the incremental common shares issuable upon the exercise of stock options. Under the treasury stock method, unexercised in-the-money stock options and warrants are assumed to be exercised at the beginning of the period or at issuance, if later. The assumed proceeds are then used to purchase common shares at the average market price during the period. Share-based payment awards that entitle their holders to receive non-forfeitable dividends before vesting are considered participating securities and are considered in the calculation of basic and diluted earnings per share.

Basic and diluted weighted average shares outstanding were as follows:

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	Three months ended September 30,		Nine mon Septem	
	2015	2014	2015	2014
Weighted average common shares	32,925,004	32,677,003	32,860,382	32,292,588
Dilutive common stock options	764,556	650,374	757,617	807,011
Weighted average common shares, assuming				
dilution	33,689,560	33,327,377	33,617,999	33,099,599

At September 30, 2015, there were outstanding options to purchase 1,252,356 shares of the Company s common stock at a weighted average exercise price of \$10.47 per share. For the three- and nine-month periods ended September 30, 2015, 163,459 and 170,891 shares of the Company s common stock, respectively, were excluded from the calculation of diluted earnings per share because the exercise prices of the stock options were greater than or equal to the average price of the common shares, and were therefore anti-dilutive.

At September 30, 2014, there were outstanding options to purchase 1,259,317 shares of the Company s common stock at a weighted average exercise price of \$7.61 per share. For the three- and nine-month periods ended September 30, 2014, 263,475 and 289,475 shares of the Company s common stock, respectively, were excluded from the calculation of diluted earnings per share because the exercise prices of the stock options were greater than or equal to the average price of the common shares, and were therefore anti-dilutive.

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6. Stock-Based Compensation

For the three months ended September 30, 2015 and 2014, the Company recorded stock-based compensation expense of \$981,000 and \$533,000, respectively, for share-based awards granted under the Second Amended and Restated 2001 Repligen Corporation Stock Plan (the 2001 Plan) and the Repligen Corporation Amended and Restated 2012 Stock Option and Incentive Plan (the 2012 Plan, and collectively with the 2001 Plan and the 1992 Repligen Corporation Stock Option Plan, the Plans). The Company recorded stock-based compensation expense of \$2,668,000 and \$1,386,000 for the nine-month periods ended September 30, 2015 and 2014, respectively, for share-based awards granted under the Plans.

The following table presents stock-based compensation expense included in the Company s consolidated statements of comprehensive income:

(In thousands)	Three months ended September 30,				Nine months ender September 30,			
	20	15	20)14	20	015	2	014
Cost of product revenue	\$	60	\$	46	\$	166	\$	136
Research and development		91		62		250		174
Selling, general and administrative	8	830		425	2	2,252	1	1,076
Total	\$ 9	981	\$	533	\$ 2	2,668	\$ 1	1,386

The 2012 Plan allows for the granting of incentive and nonqualified options to purchase shares of common stock, restricted stock, restricted stock units and other equity awards. Incentive options and restricted stock units granted to employees under the Plans generally vest over a three to five-year period, with 20%-33% vesting on the first anniversary of the date of grant and the remainder vesting in equal yearly installments thereafter. Nonqualified options issued to non-employee directors under the Plans generally vest over one year. Options granted under the Plans have a maximum term of ten years from the date of grant and generally, the exercise price of the stock options equals the fair market value of the Company s common stock on the date of grant. At September 30, 2015, options to purchase 1,252,356 shares were outstanding under the Plans. At September 30, 2015, 2,454,573 shares were available for future grant under the 2012 Plan.

The Company uses the Black-Scholes option pricing model to calculate the fair value of share-based awards on the grant date. The Company measures stock-based compensation cost at the grant date based on the estimated fair value of the award and recognizes awards with service based vesting as expense over the employee s requisite service period on a straight-line basis. The Company records the expense for share-based awards subject to performance-based milestone vesting over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates whether the achievement of a performance-based milestone is probable as of the reporting date. The Company has no awards that are subject to performance or market conditions as of September 30, 2015. The Company recognizes stock-based compensation expense for options that are ultimately expected to vest, and accordingly, such compensation expense has been adjusted for estimated forfeitures.

Information regarding option activity for the nine months ended September 30, 2015 under the Plans is summarized below:

	Options Outstanding	Ay Ex Pr	eighted- verage xercise ice Per Share	Weighted- Average Remaining Contractual Term (in years)	I	ggregate ntrinsic Value housands)
Options outstanding at January 1, 2015	1,225,117	\$	8.31			
Granted	270,532		16.57			
Exercised	(171,893)		5.24			
Forfeited/Cancelled	(71,400)		9.12			
Options outstanding at September 30, 2015	1,252,356	\$	10.47	7.08	\$	22,287
Options exercisable at September 30, 2015	504,326	\$	6.33	4.87	\$	10,853
Vested and expected to vest at September 30, 2015 (1)	1,186,665	\$	10.47	7.04	\$	21,146

(1) Represents the number of vested options as of September 30, 2015 plus the number of unvested options expected to vest as of September 30, 2015 based on the unvested outstanding options at September 30, 2015 adjusted for estimated forfeiture rates of 8% for awards granted to non-executive level employees and 3% for awards granted to executive level employees.

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (the difference between the closing price of the common stock on September 30, 2015 of \$27.85 and the exercise price of each in-the-money option) that would have been received by the option holders had all option holders exercised their options on September 30, 2015.

The weighted average grant date fair value of options granted during the nine months ended September 30, 2015 and 2014 was \$22.41 and \$11.12, respectively. The total fair value of stock options that vested during the nine months ended September 30, 2015 and 2014 was approximately \$1,862,000 and \$1,023,000, respectively.

As of September 30, 2015, there was \$7,455,000 of total unrecognized compensation cost related to unvested share-based awards. This cost is expected to be recognized over a weighted average remaining requisite service period of 2.97 years. The Company expects 682,339 unvested options to vest over the next five years.

7. Cash, Cash Equivalents and Marketable Securities

At September 30, 2015 and December 31, 2014, the Company s investments included money market funds as well as short-term and long-term marketable securities. These marketable securities are classified as available-for-sale. Marketable securities are investments with original maturities of greater than 90 days. Long-term marketable securities are securities with maturities of greater than one year. The average remaining contractual maturity of

marketable securities at September 30, 2015 is approximately 5.5 months.

Management reviewed the Company s investments as of September 30, 2015 and December 31, 2014 and concluded that there are no securities with other than temporary impairments in its investment portfolio. The Company does not intend to sell any investments in an unrealized loss position, and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases.

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Investments in marketable securities consisted of the following at September 30, 2015 (in thousands):

	September 30, 2015						
		Gros	SS	Gr	OSS		
	Amortized	Unreal	ized	Unre	alized		
	Cost	Gai	n	Lo	OSS	Fa	ir Value
Marketable securities:							
U.S. Government and agency securities	\$ 11,053	\$	4	\$		\$	11,057
Corporate and other debt securities	9,729		5		(1)		9,733
	20,782		9		(1)		20,790
Long-term marketable securities:							
U.S. Government and agency securities	1,649		2				1,651
Corporate and other debt securities							
	1,649		2				1,651
	•						
Total	\$ 22,431	\$	11	\$	(1)	\$	22,441

At September 30, 2015, the Company s investments included fourteen securities in unrealized loss positions with a total unrealized loss of approximately \$1,000 and a total fair market value of approximately \$4,920,000. All investments with gross unrealized losses have been in unrealized loss positions for less than 12 months. The unrealized losses were caused primarily by current economic and market conditions. There was no change in the credit risk of the securities. There were no realized gains or losses on the investments for the nine months ended September 30, 2015 or the nine months ended September 30, 2014.

Investments in marketable securities consisted of the following at December 31, 2014 (in thousands):

		Gross	Gross	
	Amortized	Unrealized	Unrealized	
	Cost	Gain	Loss	Fair Value
Marketable securities:				
U.S. Government and agency securities	\$ 12,716	\$ 2	\$ (2)	\$ 12,716
Corporate and other debt securities	10,373	4	(3)	10,374
	23,089	6	(5)	23,090
Long-term marketable securities:				
U.S. Government and agency securities	1,228			1,228
Corporate and other debt securities	2,326		(4)	2,322
	3,554		(4)	3,550
	·		. ,	
Total	\$ 26,643	\$ 6	\$ (9)	\$ 26,640

The contractual maturities of marketable securities at September 30, 2015 were as follows (in thousands):

	Amortized	
	Cost	Fair Value
Due in 1 year or less	\$ 20,782	\$ 20,790
Due in 1 to 2 years	1,649	1,651
	\$ 22,431	\$ 22,441

8. Fair Value Measurement

In determining the fair value of its assets and liabilities, the Company uses various valuation approaches. The Company employs a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company s assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

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- Level 1 Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access
- Level 2 Valuations based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly

Level 3 Valuations based on inputs that are unobservable and significant to the overall fair value measurement The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level input that is significant to the overall fair value measurement.

The Company s fixed income investments are comprised of obligations of U.S. government agencies and corporate marketable securities. These investments have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market based approaches and observable market inputs to determine value. These observable market inputs include reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. At least annually, the Company validates the prices provided by third party pricing services by reviewing their pricing methods and matrices, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active. The Company did not adjust or override any fair value measurements provided by the pricing services as of September 30, 2015.

The following fair value hierarchy table presents information about each major category of the Company s assets measured at fair value on a recurring basis as of September 30, 2015 (in thousands):

	Fair value Quoted prices in	e measurement at	t reporting date	using:
	active markets for identical assets o (Level	ther observable inputs	Significant unobservable inputs	Tatal
Accepta	1)	(Level 2)	(Level 3)	Total
Assets:				
Money market funds	\$ 9,543	\$	\$	\$ 9,543
U.S. Government and agency securities	8,496	4,012		12,508