LANNETT CO INC Form 10-O November 08, 2018 Table of Contents

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 AND **EXCHANGE ACT OF 1934**

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2018

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES AND 0 **EXCHANGE ACT OF 1934**

FOR THE TRANSITION PERIOD FROM

то

Commission File No. 001-31298

LANNETT COMPANY, INC.

(Exact Name of Registrant as Specified in its Charter)

State of Delaware (State of Incorporation)

23-0787699 (I.R.S. Employer I.D. No.)

9000 State Road

Philadelphia, PA 19136

(215) 333-9000

(Address of principal executive offices and telephone number)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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 every Interactive Data File required to be submitted 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 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, a smaller reporting company, or an emerging growth company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company and emerging growth company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer X

Non-accelerated filer O

Accelerated filer 0

Smaller reporting company O Emerging growth company O

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. o

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

Indicate the number of shares outstanding of each class of the registrant s common stock, as of the latest practical date.

Class Common stock, par value \$0.001 per share **Outstanding as of October 31, 2018** 38,952,752

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

LANNETT COMPANY, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	(Unaudited) September 30, 2018			June 30, 2018
ASSETS	Бері	ember 50, 2010		June 50, 2010
Current assets:				
Cash and cash equivalents	\$	150,327	\$	98,586
Accounts receivable, net		205,350		252,651
Inventories		145,915		141,635
Prepaid income taxes		1,690		15,159
Assets held for sale		13,245		13,976
Other current assets		7,859		4,863
Total current assets		524,386		526,870
Property, plant and equipment, net		195,880		233,247
Intangible assets, net		416,016		424,425
Goodwill				339,566
Deferred tax assets		99,761		22,063
Other assets		21,612		29,133
TOTAL ASSETS	\$	1,257,655	\$	1,575,304
LIABILITIES				
Current liabilities:				
Accounts payable	\$	48,558	\$	56,767
Accrued expenses	Ψ	5,732	Ψ	7,425
Accrued payroll and payroll-related expenses		10,009		7,819
Rebates payable		36,489		49,400
Royalties payable		5,878		5,955
Restructuring liability		6,911		6,706
Liabilities held for sale		2,010		0,100
Short-term borrowings and current portion of long-term debt		66,845		66.845
Total current liabilities		182,432		200,917
Long-term debt, net		760,127		772,425
Other liabilities		3,073		3,047
TOTAL LIABILITIES		945,632		976,389
Commitments and contingencies (Note 12 and 13)		,		,

STOCKHOLDERS EQUITY

Common stock (\$0.001 par value, 100,000,000 shares authorized; 38,665,268 and 38,256,839 shares issued; 37,734,758 and 37,380,517 shares outstanding at September 30, 2018 and June 30, 2018, respectively) Additional paid-in capital Retained earnings

	39	38
capital	310,135	306,817
	16,653	306,464

Accumulated other comprehensive loss	(509)	(515)
Treasury stock (930,510 and 876,322 shares at September 30, 2018 and		
June 30, 2018, respectively)	(14,295)	(13,889)
Total stockholders equity	312,023	598,915
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	\$ 1,257,655 \$	1,575,304

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

CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

(In thousands, except share and per share data)

	Three Months Ended September 30,					
	2018		2017			
Net sales	\$ 155,054	\$	154,961			
Cost of sales	87,690		79,553			
Amortization of intangibles	8,223		7,737			
Gross profit	59,141		67,671			
Operating expenses:						
Research and development expenses	9,810		7,409			
Selling, general and administrative expenses	20,588		19,038			
Acquisition and integration-related expenses			18			
Restructuring expenses	1,022		527			
Asset impairment charges	369,499					
Total operating expenses	400,919		26,992			
Operating income (loss)	(341,778)		40,679			
Other income (loss):						
Investment income	379		1,164			
Interest expense	(21,433)		(20,912)			
Other	(296)		(251)			
Total other loss	(21,350)		(19,999)			
Income (loss) before income tax	(363,128)		20,680			
Income tax expense (benefit)	(75,600)		7,423			
Net income (loss)	\$ (287,528)	\$	13,257			
Earnings (loss) per common share:						
Basic	\$ (7.65)	\$	0.36			
Diluted	\$ (7.65)	\$	0.35			
Weighted average common shares outstanding:						
Basic	37,586,327		36,992,064			
Diluted	37,586,327		37,730,656			

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

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(UNAUDITED)

(In thousands)

	Three Months Ended September 30,						
	2018			2017			
Net income (loss)	\$	(287,528)	\$	13,257			
Other comprehensive income (loss), before tax:							
Foreign currency translation gain (loss)		6		1			
Total other comprehensive income, before tax		6		1			
Income tax related to items of other comprehensive income							
Total other comprehensive income, net of tax		6		1			
Comprehensive income (loss)	\$	(287,522)	\$	13,258			

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

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY

(UNAUDITED)

(In thousands)

	Commo Shares Issued	 ount	 dditional Paid-In Capital	Retained Earnings	 ccumulated Other mprehensive Loss	Treasury Stock	S	Total tockholders Equity
Balance, June 30, 2018	38,257	\$ 38	\$ 306,817	\$ 306,464	\$ (515)	\$ (13,889)	\$	598,915
Shares issued in connection with share-based								
compensation plans	408	1	283					284
Share-based compensation			3,035					3,035
Purchase of treasury stock						(406)		(406)
Other comprehensive								
income, net of tax					6			6
ASC 606 adjustment, net of								
tax				(2,283)				(2,283)
Net loss				(287,528)				(287,528)
Balance, September 30, 2018	38,665	\$ 39	\$ 310,135	\$ 16,653	\$ (509)	\$ (14,295)	\$	312,023

	Commo	n Stock		А	dditional			Ac	cumulated Other			Total
	Shares Issued	Amo	unt		Paid-In Capital	-	Retained Earnings	Con	nprehensive Loss	T	Treasury Stock	 ockholders Equity
Balance, June 30, 2017	37,528	\$	37	\$	292,780	\$	277,774	\$	(222)	\$	(9,247)	\$ 561,122
Shares issued in connection with share-based												
compensation plans	144		1		313							314
Share-based compensation					2,189							2,189
Purchase of treasury stock											(612)	(612)
Other comprehensive												
income, net of tax									1			1
Net income							13,257					13,257
Balance, September 30,												
2017	37,672	\$	38	\$	295,282	\$	291,031	\$	(221)	\$	(9,859)	\$ 576,271

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

CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(In thousands)

		Three Months Ended September 30,			I
		2018	Septem	<i>bei 20,</i>	2017
OPERATING ACTIVITIES:					
Net income (loss)	\$	(287	,528)	\$	13,257
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating	g				
activities:					
Depreciation and amortization		14	,802		13,778
Deferred income tax expense (benefit)		(77	,698)		4,161
Share-based compensation		3	3,035		2,189
Asset impairment charges		369	,499		
Loss on sale of assets			37		234
Loss (Gain) on investment securities					(864)
Amortization of debt discount and other debt issuance costs		4	1,539		5,017
Changes in assets and liabilities which provided (used) cash:					
Accounts receivable, net		44	,127		(39,260)
Inventories		(9	9,842)		(2,786)
Prepaid income taxes		14	1,386		3,261
Other assets		(2	2,149)		(6,262)
Rebates payable		(12	2,911)		2,743
Royalties payable			(77)		(535)
Restructuring liability			205		(933)
Accounts payable		(7	(,320)		2,009
Accrued expenses		(1	,253)		543
Accrued payroll and payroll-related expenses		2	2,872		1,873
Net cash provided by (used in) operating activities		54	,724		(1,575)
INVESTING ACTIVITIES:					
Purchases of property, plant and equipment		(5	5,802)		(12,053)
Proceeds from sale of property, plant and equipment		14	1,046		15
Proceeds from sale of outstanding loan to Variable Interest Entity (VIE)		5	5,600		
Purchase of intangible asset					(2,038)
Proceeds from sale of investment securities					27,822
Purchase of investment securities					(23,840)
Net cash provided by (used in) investing activities		13	3,844		(10,094)
FINANCING ACTIVITIES:					
Repayments of long-term debt		(16	5,711)		(13,310)
Proceeds from issuance of stock			284		314
Purchase of treasury stock			(406)		(612)
Net cash used in financing activities		(16	5,833)		(13,608)
Effect on cash and cash equivalents of changes in foreign exchange rates		,	6		1
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS		51	.741		(25,276)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD		98	3,586		117,737
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$),327	\$	92,461
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			,		, , , , , , , , , , , , , , , , , , , ,
Interest paid (net of capitalized interest of \$0 and \$457 thousand for the three months					
ended September 30, 2018 and 2017, respectively)	\$	16	5,716	\$	15,714
Income taxes paid (refunded)	\$		2,282)	\$	231

Credits issued pursuant to a Settlement Agreement	\$ \$

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

2,500

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

Note 1. Interim Financial Information

The accompanying unaudited financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) for the presentation of interim financial statements and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, the unaudited financial statements do not include all the information and footnotes necessary for a comprehensive presentation of the financial position, results of operations and cash flows for the periods presented. In the opinion of management, the unaudited financial statements include all the normal recurring adjustments that are necessary for a fair presentation of the financial position, results of operations and cash flows for the three months ended September 30, 2018 are not necessarily indicative of the results that may be expected for the fiscal year ending June 30, 2019. These unaudited financial statements should be read in combination with the other Notes in this section; Management s Discussion and Analysis of Financial Condition and Results of Operations appearing in Item 2; and the Consolidated Financial Statements, including the Notes to the Consolidated Financial Statements, include in our Annual Report on Form 10-K for the fiscal year ended June 30, 2018. The Consolidated Balance Sheet as of June 30, 2018 was derived from audited financial statements.

Note 2. The Business And Nature of Operations

Lannett Company, Inc. (a Delaware corporation) and its subsidiaries (collectively, the Company or Lannett) primarily develop, manufacture, package, market and distribute solid oral and extended release (tablets and capsules), topical, nasal and oral solution finished dosage forms of drugs that address a wide range of therapeutic areas. Certain of these products are manufactured by others and distributed by the Company. The Company also manufactures active pharmaceutical ingredients through its Cody Laboratories, Inc. (Cody Labs) subsidiary primarily for use in its finished dosage forms. In the first quarter of Fiscal 2019, the Company approved a plan to sell the Cody API business. See Note 22 Assets Held for Sale for more information.

On November 25, 2015, the Company completed the acquisition of Kremers Urban Pharmaceuticals, Inc. (KUPI), the former U.S. specialty generic pharmaceuticals subsidiary of global biopharmaceuticals company UCB S.A. (UCB). KUPI is a specialty pharmaceuticals manufacturer focused on the development of products that are difficult to formulate or utilize specialized delivery technologies.

The Company operates pharmaceutical manufacturing plants in Philadelphia, Pennsylvania; Cody, Wyoming; Carmel, New York and Seymour, Indiana. The Company s customers include generic pharmaceutical distributors, drug wholesalers, chain drug stores, private label distributors, mail-order pharmacies, other pharmaceutical manufacturers, managed care organizations, hospital buying groups, governmental entities and health maintenance organizations.

Note 3. Summary of Significant Accounting Policies

Basis of Presentation

The Consolidated Financial Statements have been prepared in conformity with generally accepted accounting principles in the United States (U.S. GAAP).

Principles of consolidation

The Consolidated Financial Statements include the accounts of Lannett Company, Inc. and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated.

Business Combinations

Acquired businesses are accounted for using the acquisition method of accounting, which requires that the assets acquired and liabilities assumed be recorded at the date of acquisition at their respective estimated fair values. The fair values and useful lives assigned to each class of assets acquired and liabilities assumed are based on, among other factors, the expected future period of benefit of the asset, the various characteristics of the asset and projected future cash flows. Significant judgment is employed in determining the assumptions utilized as of the acquisition date and for each subsequent measurement period. Accordingly, changes in assumptions described above could have a material impact on our consolidated results of operations.

Use of estimates

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 at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions are required in the determination of revenue recognition and sales deductions for estimated chargebacks, rebates, returns and other adjustments including a provision for the Company s liability under the Medicare Part D program. Additionally, significant estimates and assumptions are required when determining the fair value of long-lived assets, including goodwill and intangible assets, income taxes, contingencies and share-based compensation.

Because of the inherent subjectivity and complexity involved in these estimates and assumptions, actual results could differ from those

estimates.

Foreign currency translation

The Consolidated Financial Statements are presented in U.S. Dollars, the reporting currency of the Company. The financial statements of the Company's foreign subsidiary are maintained in local currency and translated into U.S. dollars at the end of each reporting period. Assets and liabilities are translated at period-end exchange rates, while revenues and expenses are translated at average exchange rates during the period. The adjustments resulting from the use of differing exchange rates are recorded as part of stockholders equity in accumulated other comprehensive income (loss). Gains and losses resulting from transactions denominated in foreign currencies are recognized in the Consolidated Statements of Operations under Other income (loss). Amounts recorded due to foreign currency fluctuations are immaterial to the Consolidated Financial Statements.

Cash and cash equivalents

The Company considers all highly liquid investments with original maturities less than or equal to three months at the date of purchase to be cash and cash equivalents. Cash and cash equivalents are stated at cost, which approximates fair value, and consist of bank deposits and certificates of deposit that are readily convertible into cash. The Company maintains its cash deposits and cash equivalents at well-known, stable financial institutions. Such amounts frequently exceed insured limits.

Investment securities

The Company s investment securities consisted of publicly-traded equity securities which were classified as trading investments. Investment securities were recorded at fair value based on quoted market prices from broker or dealer quotations or transparent pricing sources at each reporting date. Realized and unrealized gains and losses are included in the Consolidated Statements of Operations under Other income (loss). In May 2018, the Company liquidated the remainder of the investment securities portfolio. As of September 30, 2018 and June 30, 2018, the

Company does not own investment securities.

Allowance for doubtful accounts

The Company continuously monitors collections and payments from its customers and maintains a provision for estimated credit losses. The Company determines its allowance for doubtful accounts by considering a number of factors, including the length of time balances are past due, the Company s previous loss history, the customer s current ability to pay its obligations to the Company and the condition of the general economy and the industry as a whole. The Company writes off accounts receivable when they are determined to be uncollectible.

Inventories

Inventories are stated at the lower of cost or net realizable value by the first-in, first-out method. Inventories are regularly reviewed and write-downs for excess and obsolete inventory are recorded based primarily on current inventory levels, expiration date and estimated sales forecasts.

Property, Plant and Equipment

Property, plant and equipment are stated at cost less accumulated depreciation. Depreciation is computed on a straight-line basis over the assets estimated useful lives.

Intangible Assets

Definite-lived intangible assets are stated at cost less accumulated amortization. Amortization of definite-lived intangible assets is computed on a straight-line basis over the assets estimated useful lives, generally for periods ranging from 10 to 15 years. The Company continually evaluates the reasonableness of the useful lives of these assets. Indefinite-lived intangible assets are not amortized, but instead are tested at least annually for impairment. Costs to renew or extend the term of a recognized intangible asset are expensed as incurred.

Valuation of Long-Lived Assets, including Intangible Assets other than Goodwill

The Company s long-lived assets primarily consist of property, plant and equipment and definite and indefinite-lived intangible assets. Property, plant and equipment and definite-lived intangible assets are reviewed for impairment whenever events or changes in circumstances (triggering events) indicate that the carrying amount of the asset may not be recoverable. If a triggering event is determined to have occurred, the asset s carrying value is compared to the future undiscounted cash flows expected to be generated by the asset. If the carrying value exceeds the undiscounted cash flows of the asset, then impairment exists. Indefinite-lived intangible assets are tested for impairment at least annually during the fourth quarter of each fiscal year or more frequently if events or triggering events indicate that the asset might be impaired.

An impairment loss is measured as the excess of the asset s carrying value over its fair value, which in most cases is calculated using a discounted cash flow model. Discounted cash flow models are highly reliant on various assumptions which are considered Level 3 inputs, including estimates of future cash flows (including long-term growth rates), discount rates and the probability of achieving the estimated cash flows.

In-Process Research and Development

Amounts allocated to in-process research and development in connection with a business combination are recorded at fair value and are considered indefinite-lived intangible assets subject to impairment testing in accordance with the Company s impairment testing policy for indefinite-lived intangible assets. As products in development are approved for sale, amounts will be allocated to product rights and will be amortized over their estimated useful lives. Definite-lived intangible assets are amortized over the expected lives of the related assets. The judgments made in determining the estimated fair value of in-process research and development, as well as asset lives, can materially impact our results of operations. The Company s fair value assessments are highly reliant on various assumptions which are considered Level 3 inputs, including estimates of future cash flows (including long-term growth rates), discount rates and the probability of achieving the estimated cash flows.

Goodwill

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Goodwill, which represented the excess of purchase price over the fair value of net assets acquired, was carried at cost. Goodwill is tested for impairment on an annual basis on the first day of the fourth quarter of each fiscal year or more frequently if events or triggering events indicate that the asset might be impaired. The Company utilizes a quantitative assessment to determine the fair value of our reporting unit (generic pharmaceuticals) based on market data as well as projected cash flows. If the carrying value of our reporting unit exceeds its fair value, the difference will be recorded as a goodwill impairment, not to exceed the carrying amount of goodwill. The Company s fair value assessments are highly reliant on various assumptions which are considered Level 3 inputs, including estimates of future cash flows (including long-term growth rates), discount rates and the probability of achieving the estimated cash flows. The judgments made in determining the estimated fair value of goodwill can materially impact our results of operations.

Segment Information

The Company operates in one reportable segment, generic pharmaceuticals. As such, the Company aggregates its financial information for all products. The following table identifies the Company s net sales by medical indication for the three months ended September 30, 2018 and 2017:

(In thousands)	Three Months Ended September 30,				
Medical Indication	2018		2017		
Antibiotic	\$ 4,089	\$	3,349		
Anti-Psychosis	10,889		14,991		
Cardiovascular	21,770		11,306		
Central Nervous System	7,197		8,818		
Gallstone	2,214		6,564		
Gastrointestinal	15,040		14,553		
Glaucoma	548		2,668		
Migraine	9,737		15,015		
Muscle Relaxant	3,179		3,791		
Pain Management	4,947		5,761		
Respiratory	1,015		1,647		
Thyroid Deficiency	53,878		47,214		
Urinary	1,552		2,997		
Other	14,338		12,696		
Contract manufacturing revenue	4,661		3,591		
Total	\$ 155,054	\$	154,961		

The Company sells its products to customers in various distribution channels. The table below presents the Company s net sales to each distribution channel for the three months ended September 30:

(In thousands) Customer Distribution Channel	Se	ptember 30, 2018	S	eptember 30, 2017
Wholesaler/Distributor	\$	116,354	\$	120,801
Retail Chain		25,041		18,768
Mail-Order Pharmacy		8,998		11,801
Contract manufacturing revenue		4,661		3,591
Total	\$	155,054	\$	154,961

Customer, Supplier and Product Concentration

The following table presents the percentage of total net sales, for the three months ended September 30, 2018 and 2017, for one of the Company s products, defined as products containing the same active ingredient or combination of ingredients, which accounted for at least 10% of net sales in any of those periods:

Product 1	35%	30%

The following table presents the percentage of total net sales, for the three months ended September 30, 2018 and 2017, for certain of the Company s customers which accounted for at least 10% of net sales in any of those periods:

	2018	2017
Customer A	29%	27%
Customer B	18%	20%

The Company s primary finished goods inventory supplier is Jerome Stevens Pharmaceuticals, Inc. (JSP), in Bohemia, New York. Purchases of finished goods inventory from JSP accounted for approximately 32% and 33% of the Company s inventory purchases during the three months ended September 30, 2018 and 2017, respectively. See Note 21 Material Contracts with Suppliers for more information.

Revenue Recognition

On July 1, 2018, the Company adopted Accounting Standards Codification (ASC) Topic 606, *Revenue from Contracts with Customers*, which superseded ASC Topic 605, *Revenue Recognition*. Under ASC 606, the Company recognizes revenue when (or as) we satisfy our performance obligations by transferring a promised good or service to a customer at an amount that reflects the consideration the Company is expected to be entitled. Our revenue consists almost entirely of sales of our pharmaceutical products to customers, whereby we ship product to a customer pursuant to a purchase order. Revenue contracts such as these do not generally give rise to contract assets or contract liabilities because: (i) the underlying contracts generally have only a single performance obligation and (ii) we do not generally receive consideration until the performance obligation is fully satisfied. The new revenue standard impacts the timing of the Company s revenue recognition by requiring recognition of certain contract manufacturing arrangements to change from upon shipment or delivery to over time. However, the recognition of these arrangements over time does not currently have a material impact on the Company s consolidated results of operations or financial position. The Company adopted ASC 606 using the modified retrospective method. Refer to the *Recent Accounting Pronouncements* section of this footnote for further discussion of the impact of the adoption.

When revenue is recognized, a simultaneous adjustment to gross sales is made for estimated chargebacks, rebates, returns, promotional adjustments and other potential adjustments. These provisions are primarily estimated based on historical experience, future expectations, contractual arrangements with wholesalers and indirect customers and other factors known to management at the time of accrual. Accruals for provisions are presented in the Consolidated Financial Statements as a reduction to gross sales with the corresponding reserve presented as a reduction of accounts receivable or included as rebates payable, depending on the nature of the reserve.

Provisions for chargebacks, rebates, returns and other adjustments require varying degrees of subjectivity. While rebates generally are based on contractual terms and require minimal estimation, chargebacks and returns require management to make more subjective assumptions. Each major category is discussed in detail below:

Chargebacks

The provision for chargebacks is the most significant and complex estimate used in the recognition of revenue. The Company sells its products directly to wholesale distributors, generic distributors, retail pharmacy chains and mail-order pharmacies. The Company also sells its products indirectly to independent pharmacies, managed care organizations, hospitals, nursing homes and group purchasing organizations, collectively referred to as indirect customers. The Company enters into agreements with its indirect customers to establish pricing for certain products. The indirect customers then independently select a wholesaler from which to purchase the products. If the price paid by the indirect customers is lower than the price paid by the wholesaler, the Company will provide a credit, called a chargeback, to the wholesaler for the difference between the contractual price with the indirect customers and the wholesaler purchase price. The provision for chargebacks is based on expected sell-through levels by the Company s wholesale customers to the indirect customers and estimated wholesaler inventory levels. As sales to the large wholesale customers, such as Cardinal Health, AmerisourceBergen and McKesson increase (decrease), the reserve for chargebacks will also generally increase (decrease). However, the size of the increase (decrease) depends on product mix and the amount of sales made to indirect customers with which the Company has specific chargeback agreements. The Company continually monitors the reserve for chargebacks and makes adjustments when management believes that expected chargebacks may differ from the actual chargeback reserve.

Rebates

Rebates are offered to the Company s key chain drug store, distributor and wholesaler customers to promote customer loyalty and increase product sales. These rebate programs provide customers with credits upon attainment of pre-established volumes or attainment of net sales milestones for a specified period. Other promotional programs are incentive programs offered to the customers. Additionally, as a result of the Patient Protection and Affordable Care Act (PPACA) enacted in the U.S. in March 2010, the Company participates in a new cost-sharing program for certain Medicare Part D beneficiaries designed primarily for the sale of brand drugs and certain generic drugs if their FDA approval was granted under a New Drug Application (NDA) or 505(b) NDA versus an abbreviated new drug application (ANDA). Because our drugs used for the treatment of thyroid deficiency and our Morphine Sulfate Oral Solution product were both approved by the FDA as 505(b)(2) NDAs, they are considered brand drugs for purposes of the PPACA. Drugs purchased within the Medicare Part D coverage gap (commonly referred to as the donut hole) result in additional rebates. The Company estimates the reserve for rebates and other promotional credit programs based on the specific terms in each agreement when revenue is recognized. The reserve for rebates increases (decreases) as sales to certain wholesale and retail customers increase (decrease). However, since these rebate programs are not identical for all customers, the size of the reserve will depend on the mix of sales to customers that are eligible to receive rebates.

Returns

Consistent with industry practice, the Company has a product returns policy that allows customers to return product within a specified time period prior to and subsequent to the product s expiration date in exchange for a credit to be applied to future purchases. The Company s policy requires that the customer obtain pre-approval from the Company for any qualifying return. The Company estimates its provision for returns based on historical experience, changes to business practices, credit terms and any extenuating circumstances known to management. While historical experience has allowed for reasonable estimations in the past, future returns may or may not follow historical trends. The Company continually monitors the reserve for returns and makes adjustments when management believes that actual product returns may differ from the established reserve. Generally, the reserve for returns increases as net sales increase.

Other Adjustments

Other adjustments consist primarily of price adjustments, also known as shelf-stock adjustments and price protections, which are both credits issued to reflect increases or decreases in the invoice or contract prices of the Company s products. In the case of a price decrease, a credit is given for product remaining in customer s inventories at the time of the price reduction. Contractual price protection results in a similar credit when the invoice or contract prices of the Company s products increase, effectively allowing customers to purchase products at previous prices for a specified period of time. Amounts recorded for estimated shelf-stock adjustments and price protections are based upon specified terms with direct customers, estimated changes in market prices and estimates of inventory held by customers. The Company regularly monitors these and other factors and evaluates the reserve as additional information becomes available. Other adjustments also include prompt payment discounts and failure-to-supply adjustments. If the Company is unable to fulfill certain customer orders, the customer can purchase products from our competitors at their prices and charge the Company for any difference in our contractually agreed upon prices.

Cost of Sales, including Amortization of Intangibles

Cost of sales includes all costs related to bringing products to their final selling destination, which includes direct and indirect costs, such as direct material, labor and overhead expenses. Additionally, cost of sales includes product royalties, depreciation, amortization and costs to renew or extend recognized intangible assets, freight charges and other shipping and handling expenses.

Research and Development

Research and development costs are expensed as incurred, including all production costs until a drug candidate is approved by the Food and Drug Administration (FDA). Research and development expenses include costs associated with internal projects as well as costs associated with third-party research and development contracts.

Contingencies

Loss contingencies, including litigation-related contingencies, are included in the Consolidated Statements of Operations when the Company concludes that a loss is both probable and reasonably estimable. Legal fees for litigation-related matters are expensed as incurred and included in the Consolidated Statements of Operations under the Selling, general and administrative expense line item.

Restructuring Costs

The Company records charges associated with approved restructuring plans to remove duplicative headcount and infrastructure associated with business acquisitions or to simplify business processes. Restructuring charges can include severance costs to eliminate a specified number of employees, infrastructure charges to vacate facilities and consolidate operations and contract cancellation costs. The Company records restructuring charges based on estimated employee terminations, site closure and consolidation plans. The Company accrues severance and other employee separation costs under these actions when it is probable that a liability exists and the amount is reasonably estimable.

Share-based Compensation

Share-based compensation costs are recognized over the vesting period, using a straight-line method, based on the fair value of the instrument on the date of grant less an estimate for expected forfeitures. The Company uses the Black-Scholes valuation model to determine the fair value of stock options, the stock price on the grant date to value restricted stock and the Monte-Carlo simulation model to determine the fair value of performance-based shares. The Black-Scholes valuation and Monte-Carlo simulation models include various assumptions, including the expected volatility, the expected life of the award, dividend yield and the risk-free interest

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rate as well as performance assumptions of peer companies. These assumptions involve inherent uncertainties based on market conditions which are generally outside the Company s control. Changes in these assumptions could have a material impact on share-based compensation costs recognized in the consolidated financial statements.

Self-Insurance

Effective January 1, 2017, the Company self-insures for certain employee medical and prescription benefits. The Company also maintains stop loss coverage with third party insurers to limit its total liability exposure. The liability for self-insured risks is primarily calculated using independent third party actuarial valuations which take into account actual claims, claims growth and claims incurred but not yet reported. Actual experience, including claim frequency and severity as well as health-care inflation, could result in different liabilities than the amounts currently recorded. The liability for self-insured risks under this plan as of September 30, 2018 totaled \$2.2 million and was not material to the financial position of the Company as of June 30, 2018.

Income Taxes

The Company uses the liability method to account for income taxes as prescribed by Accounting Standards Codification (ASC) 740, Income Taxes. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities as measured by the enacted tax rates which will be in effect when these differences reverse. Deferred tax expense (benefit) is the result of changes in deferred tax assets and liabilities. Deferred income tax assets and liabilities are adjusted to recognize the effects of changes in tax laws or enacted tax rates in the period during which they are signed into law. The factors used to assess the likelihood of realization are the Company s forecast of future taxable income and available tax planning strategies that could be implemented to realize the net deferred tax assets. Under ASC 740, Income Taxes, a valuation allowance is required when it is more likely than not that all or some portion of the deferred tax assets will not be realized through generating sufficient future taxable income. Failure to achieve forecasted taxable income in applicable tax jurisdictions could affect the ultimate realization of deferred tax assets and could result in an increase in the Company s effective tax rate on future earnings.

The Company may recognize the tax benefit from an uncertain tax position claimed on a tax return only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position should be measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. The authoritative accounting standards also provide guidance on de-recognition, classification, interest and penalties on income taxes, accounting in interim periods and requires increased disclosures.

On December 22, 2017, President Trump signed the Tax Cut and Jobs Act legislation (2017 Tax Reform) into law, which included a broad range of tax reform provisions affecting businesses, including corporate tax rates, business deductions and international tax provisions. Many of these provisions significantly differ from the then-current U.S. tax law, resulting in pervasive financial reporting implications. As a result of the new law, the SEC issued Staff Accounting Bulletin No. 118 (SAB 118) to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed in reasonable detail to complete the accounting for certain income tax effects of 2017 Tax Reform. SAB 118 requires registrants to report the tax effects of 2017 Tax Reform, inclusive of provisional amounts for which the accounting is incomplete but a reasonable estimate can be determined. SAB 118 also allows for a measurement period of up to one year in cases where a registrant reports a provisional amount or is unable to reasonably estimate the impact of 2017 Tax Reform.

Earnings (Loss) Per Common Share

Basic earnings (loss) per common share is computed by dividing net income (loss) by the weighted average number of shares outstanding during the period. Diluted earnings (loss) is computed by dividing net income (loss) by the weighted average number of shares outstanding during the period including additional shares that would have been outstanding related to potentially dilutive securities. These potentially dilutive securities consist of stock options, unvested restricted stock, performance-based shares and an outstanding warrant. Anti-dilutive securities are excluded from the calculation. Dilutive shares are also excluded in the calculation in periods of net loss because the effect of including such securities would be anti-dilutive.

Comprehensive Income (Loss)

Comprehensive income (loss) includes all changes in equity during a period except those that resulted from investments by or distributions to the Company s stockholders. Other comprehensive income (loss) refers to gains and losses that are included in comprehensive income (loss), but excluded from income (loss) for all amounts are recorded directly as an adjustment to stockholders equity.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued ASU 2014-09, which created ASC Topic 606 *Revenue from Contracts with Customers*. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The authoritative guidance is effective for annual reporting periods beginning after December 15, 2017. Based on a review of the contracts representing a substantial portion of our revenues, which is primarily generated from product sales, the Company determined that the updated guidance does not have a material impact on our disclosures or the timing and recognition of our revenues. Under the new standard, the Company will need to estimate certain amounts as variable consideration, specifically any failure-to-supply adjustments at the point of product sale in future periods.

The new revenue standard also impacts the timing of the Company s revenue recognition by requiring recognition of certain contract manufacturing arrangements to change from upon shipment or delivery to over time. However, the recognition of these arrangements over time does not currently have a material impact on the Company s consolidated results of operations or financial position.

The cumulative impact of the adoption of ASC 606 resulted in a \$2.3 million adjustment, net of tax, to opening retained earnings.

In February 2016, the FASB issued ASU 2016-02, Leases. ASU 2016-02 requires an entity to recognize right-of-use assets and liabilities on its balance sheet for all leases with terms longer than 12 months. Lessees and lessors are required to disclose quantitative and qualitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period and requires a modified retrospective application, with early adoption permitted. The Company is currently in the process of assessing the impact this guidance will have on the consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows Classification of Certain Cash Receipts and Cash Payments. ASU 2016-15 addresses how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The standard was adopted on July 1, 2018 and did not have an impact on the Company s consolidated financial statements.

Note 4. Restructuring Charges

Cody Restructuring Program

On June 29, 2018, the Company announced a restructuring plan with respect to Cody Labs (the Cody Restructuring Plan). The plan focuses on a more select set of opportunities which will result in streamlined operations, improved efficiencies and a reduced cost structure. The Company currently estimates that it will incur approximately \$5.0 million of total costs to implement the Cody Restructuring Plan, comprised primarily of approximately \$3.5 million of severance and employee-related costs.

The expenses associated with the Cody Restructuring Plan included in restructuring expenses during the three months ended September 30, 2018 were as follows:

(In thousands)	onths Ended ber 30, 2018
Employee separation costs	\$ 144
Facility closure costs	
Total	\$ 144

A reconciliation of the changes in restructuring liabilities associated with the Cody Restructuring Plan from June 30, 2018 through September 30, 2018 is set forth in the following table:

	Employee		Facility Closure		
(In thousands)	Separation Costs		Costs Costs		Total
Balance at June 30, 2018	\$	3,092	\$	\$	3,092
Restructuring Charges		144			144
Payments		(313)			(313)
Balance at September 30, 2018	\$	2,923		\$	2,923

2016 Restructuring Program

On February 1, 2016, in connection with the acquisition of KUPI, the Company announced a plan related to the future integration of KUPI and the Company s operations (the 2016 Restructuring Program). The plan focuses on the closure of KUPI s corporate functions and the consolidation of manufacturing, sales, research and development and distribution functions. The Company estimates that it will incur an aggregate of up to approximately \$19.0 million in restructuring charges for actions that have been announced or communicated since the 2016 Restructuring Program began. Of this amount, approximately \$10.0 million relates to employee separation costs, approximately \$1.0 million relates to contract termination costs and approximately \$8.0 million relates to facility closure costs and other actions. The 2016 Restructuring Program is expected to be completed by the end of Fiscal 2019. The expenses associated with the restructuring program included in restructuring expenses during the three months ended September 30, 2018 and 2017 were as follows:

	Т	Three		Three		
	Months Ended		Months Ended			Months Ended
(In thousands)	Septemb	er 30, 2018	Se	ptember 30, 2017		
Employee separation costs	\$	414	\$	(590)		
Facility closure costs		464		1,117		
Total	\$	878	\$	527		

In the first quarter of Fiscal 2018, the Company decided to retain certain employees who were previously included in the 2016 Restructuring Program. As a result, the Company reversed all previous charges incurred related to these employees.

A reconciliation of the changes in restructuring liabilities associated with the 2016 Restructuring Program from June 30, 2018 through September 30, 2018 is set forth in the following table:

	Employee		Fa	acility Closure	
(In thousands)	Sepa	aration Costs		Costs	Total
Balance at June 30, 2018	\$	3,614	\$		\$ 3,614
Restructuring Charges (Credits)		414		464	878
Payments		(40)		(464)	(504)
Balance at September 30, 2018	\$	3,988	\$		\$ 3,988

Note 5. Accounts Receivable

Accounts receivable consisted of the following components at September 30, 2018 and June 30, 2018:

(In thousands)	September 30, 2018	June 30, 2018
Gross accounts receivable	\$ 434,940	\$ 503,175
Less Chargebacks reserve	(125,576)	(153,034)
Less Rebates reserve	(34,136)	(33,102)
Less Returns reserve	(44,361)	(43,059)

Less Other deductions	(24,300)	(20,021)
Less Allowance for doubtful accounts	(1,217)	(1,308)
Accounts receivable, net	\$ 205,350 \$	252,651

For the three months ended September 30, 2018, the Company recorded a provision for chargebacks, rebates (including rebates presented as rebates payable), returns and other deductions of \$277.9 million, \$64.7 million, \$7.3 million and \$13.9 million, respectively. For the three months ended September 30, 2017, the Company recorded a provision for chargebacks, rebates (including rebates presented as rebates payable), returns and other deductions of \$254.7 million, \$78.5 million and \$12.4 million, respectively.

The following table identifies the activity and ending balances of each major category of revenue-related reserve for the three months ended September 30, 2018 and 2017:

Reserve Category						
(In thousands)	Cl	nargebacks	Rebates	Returns	Other	Total
Balance at June 30, 2018	\$	153,034	\$ 82,502	\$ 43,059	\$ 20,021	\$ 298,616
Adjustment related to adoption of ASC 606					3,536	3,536
Current period provision		277,949	64,749	7,347	13,889	363,934
Credits issued during the period		(305,407)	(76,626)	(6,045)	(13,146)	(401,224)
Balance at September 30, 2018	\$	125,576	\$ 70.625	\$ 44.361	\$ 24,300	\$ 264.862

Reserve Category						
(In thousands)	Ch	argebacks	Rebates	Returns	Other	Total
Balance at June 30, 2017	\$	79,537	\$ 87,616	\$ 42,135	\$ 11,096	\$ 220,384
Current period provision		254,689	78,455	10,437	12,364	355,945
Credits issued during the period		(254,952)	(73,422)	(7,151)	(9,403)	(344,928)
Balance at September 30, 2017	\$	79,274	\$ 92,649	\$ 45,421	\$ 14,057	\$ 231,401

For the three months ending September 30, 2018 and 2017, as a percentage of gross sales the provision for chargebacks was 54.0% and 50.2%, the provision for rebates was 12.6% and 15.5%, the provision for returns was 1.4% and 2.1% and the provision for other adjustments was 2.7% and 2.4%, respectively.

On July 1, 2018, the Company adopted ASC 606 which resulted in a \$3.2 million pre-tax adjustment to opening retained earnings and accounts receivable, of which \$3.5 million related to failure-to-supply reserves offset by \$0.3 million related to the timing of recognition of certain contract manufacturing arrangements.

The decrease in total reserves, primarily within the chargebacks and rebates categories, from June 30, 2018 to September 30, 2018 was mainly attributable to decreased net sales in the first quarter of Fiscal 2019 as compared to the fourth quarter of Fiscal 2018. The activity in the Other category for the three months ended September 30, 2018 and 2017 includes, shelf-stock, shipping and other sales adjustments including prompt payment discounts and failure-to-supply adjustments. Historically, we have not recorded any material amounts in the current period related to reversals or additions of prior period reserves. If the Company were to record a material reversal or addition of any prior period reserve amount, it would be separately disclosed.

Note 6. Inventories

Inventories at September 30, 2018 and June 30, 2018 consisted of the following:

(In thousands)	September 30, 2018	June 30, 2018	
Raw Materials	\$ 61,218	\$ 64,64	47
Work-in-process	22,204	19,98	83

Finished Goods	62,493	57,005
Total	\$ 145,915 \$	141,635

Inventory balances were written-down by \$14.2 million and \$11.9 million at September 30, 2018 and June 30, 2018, respectively for excess and obsolete inventory amounts. During the three months ended September 30, 2018 and 2017, the Company recorded write-downs to net realizable value for excess and obsolete inventory of \$3.4 million and \$2.2 million, respectively.

In the first quarter of Fiscal 2019, the Company approved a plan to sell the Cody API business. As such, all assets, including inventory totaling \$5.6 million, and liabilities associated with the Cody API business are recorded in the assets and liabilities held for sale captions in the Consolidated Balance Sheet as of September 30, 2018. See Note 22 Assets Held for Sale for more information.

Note 7. Property, Plant and Equipment

Property, plant and equipment at September 30, 2018 and June 30, 2018 consisted of the following:

		September 30,		June 30,	
(In thousands)	Useful Lives	2018		2018	
Land		\$ 2,2	83 \$	2,900	
Building and improvements	10 - 39 years	87,2	.11	105,041	
Machinery and equipment	5 - 10 years	155,3	71	173,988	
Furniture and fixtures	5 - 7 years	3,6	41	4,099	
Less accumulated depreciation		(76,9	(02)	(89,996)	
		171,6	04	196,032	
Construction in progress		24,2	.76	37,215	
Property, plant and equipment, net		\$ 195,8	80 \$	233,247	

Depreciation expense for the three months ended September 30, 2018 and 2017 was \$6.6 million and \$5.7 million, respectively.

In the first quarter of Fiscal 2019, the Company approved a plan to sell the Cody API business. As such, all assets, including property, plant and equipment totaling \$36.5 million, and liabilities associated with the Cody API business are recorded in the assets and liabilities held for sale captions in the Consolidated Balance Sheet as of September 30, 2018. In addition, as part of the held for sale classification, the Company is required to record the assets of the Cody API business at fair value less costs to sell. The Company performed a fair value analysis which resulted in a \$29.9 million impairment of the Cody API property, plant and equipment assets. See Note 22 Assets Held for Sale for more information. During the three months ended September 30, 2017, the Company had no impairment charges related to property, plant and equipment.

Property, plant and equipment, net included amounts held in foreign countries in the amount of \$1.7 million and \$1.1 million at September 30, 2018 and June 30, 2018, respectively.

Note 8. Fair Value Measurements

The Company s financial instruments recorded in the Consolidated Balance Sheets include cash and cash equivalents, accounts receivable, accounts payable, accrued expenses and debt obligations. Included in cash and cash equivalents are certificates of deposit with maturities less than or equal to three months at the date of purchase and money market funds. The carrying value of certain financial instruments, primarily cash and cash equivalents, accounts payable, accounts payable and accrued expenses, approximate their estimated fair values based upon the short-term nature of their maturity dates.

The Company follows the authoritative guidance of ASC Topic 820 Fair Value Measurements and Disclosures. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The authoritative guidance also establishes

a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The Company s financial assets and liabilities measured at fair value are entirely within Level 1 of the hierarchy as defined below:

Level 1 Quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity can access at the measurement date.

Level 2 Directly or indirectly observable inputs, other than quoted prices, such as quoted prices for similar assets or liabilities; quoted prices for identical or similar instruments in markets that are not active; or model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3 Unobservable inputs that are supported by little or no market activity and that are material to the fair value of the asset or liability. Financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation are examples of Level 3 assets and liabilities.

If the inputs used to measure the financial assets and liabilities fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

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Financial Instruments Disclosed, But Not Reported, at Fair Value

The fair value of our long-term debt was approximately \$786 million and \$893 million as of September 30, 2018 and June 30, 2018, respectively. We estimate the fair value of our debt utilizing market quotations for debt that have quoted prices in active markets. Since our debt does not trade on a daily basis in an active market, the fair value estimates are based on market observable inputs based on borrowing rates currently available for debt with similar terms and average maturities (Level 2).

Note 9. Investment Securities

The Company uses the specific identification method to determine the cost of securities sold, which consisted entirely of securities classified as trading.

In May 2018, the Company liquidated the remainder of the investment securities portfolio. As of September 30, 2018 and June 30, 2018, the Company does not own investment securities.

The Company had a net gain on investment securities of \$864 thousand during the three months ended September 30, 2017, which included an unrealized gain related to securities still held at September 30, 2017 of \$37 thousand.

Note 10. Goodwill and Intangible Assets

The changes in the carrying amount of goodwill for the three months ended September 30, 2018 are as follows:

(In thousands)	Generic Pharmaceuticals		
Balance at June 30, 2018	\$ 339,566		
Goodwill acquired			
Impairment	(339,566)		
Balance at September 30, 2018	\$		

On August 17, 2018, JSP notified the Company that it will not extend or renew the JSP Distribution Agreement when the current term expires on March 23, 2019. The Company determined that JSP s decision represented a triggering event under U.S. GAAP to perform an analysis to determine the potential for impairment of goodwill. On October 4, 2018, the Company completed the analysis based on market data and concluded a full impairment of goodwill was required.

Intangible assets, net as of September 30, 2018 and June 30, 2018, consisted of the following:

	Weighted	Gross Carrying Amount Accumulated		Amortization Intangih		Assets, Net	
(In thousands)	Avg. Life (Yrs.)	September 30, 2018	June 30, 2018	September 30, 2018	June 30, 2018	September 30, 2018	June 30, 2018
Definite-lived:							
Cody Labs import license	15	\$	\$ 581	\$	\$ (386)	\$	\$ 195
KUPI product rights	15	416,154	416,154	(76,776)	(69,840)	339,378	346,314
KUPI trade name	2	2,920	2,920	(2,920)	(2,920)		
KUPI other intangible							
assets	15	19,000	19,000	(3,612)	(3,295)		