MIMEDX GROUP, INC. Form 10-Q November 06, 2015

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 001-35887

MIMEDX GROUP, INC.

(Exact name of registrant as specified in its charter)

Florida 26-2792552

(State or other jurisdiction of incorporation) (I.R.S. Employer Identification Number)

1775 West Oak Commons Ct NE 30062

Marietta, GA

(Address of principal executive offices) (Zip Code)

(770) 651-9100

(Registrant's telephone number, including area code)

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 definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Non-accelerated filer "

Large accelerated filer " Accelerated filer x (Do not check if a smaller Smaller reporting company "

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

As of October 15, 2015, there were 108,962,400 shares of the registrant's common stock outstanding.

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#### Forward-Looking Statements

This Form 10-Q and certain information incorporated herein by reference contain forward-looking statements and information within the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, and Section 21E of the Securities Exchange Act of 1934. This information includes assumptions made by, and information currently available to management, including statements regarding future economic performance and financial condition, liquidity and capital resources, acceptance of our products by the market, and management's plans and objectives. In addition, certain statements included in this and our future filings with the Securities and Exchange Commission ("SEC"), in press releases, and in oral and written statements made by us or with our approval, which are not statements of historical fact, are forward-looking statements. Words such as "may," "could," "should," "would," "believe," "expect," "expectation," "anticipate," "estimate," "intend," "seeks," "plan," "project," "will," "should," and other words or expressions of similar meaning are intended by us to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are found at various places throughout this report and in the documents incorporated herein by reference. These statements are based on our current expectations about future events or results and information that is currently available to us, involve assumptions, risks, and uncertainties, and speak only as of the date on which such statements are made.

Our actual results may differ materially from those expressed or implied in these forward-looking statements. Factors that may cause such a difference include, but are not limited to, those discussed in Part II, Item 1A, "Risk Factors," below and in our most recent Annual Report on Form 10-K, as well as other reports we file with the SEC. Except as expressly required by the federal securities laws, we undertake no obligation to update any such factors, or to publicly announce the results of, or changes to any of the forward-looking statements contained herein to reflect future events, developments, changed circumstances, or for any other reason.

As used herein, the terms "MiMedx," "the Company," "we," "our" and "us" refer to MiMedx Group, Inc., a Florida corporatio and its consolidated subsidiaries as a combined entity, except where it is clear that the terms mean only MiMedx Group, Inc.

#### Part I - FINANCIAL INFORMATION

#### Item 1. Condensed Consolidated Financial Statements

# MIMEDX GROUP, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share data)

	September 30, 2015 (unaudited)	December 3 2014	1,
ASSETS			
Current assets:			
Cash and cash equivalents	\$41,073	\$46,582	
Short term investments	6,500	5,750	
Accounts receivable, net	46,778	26,672	
Inventory, net	5,653	5,133	
Prepaid expenses and other current assets	2,741	1,540	
Total current assets	102,745	85,677	
Investments		3,250	
Property and equipment, net of accumulated depreciation	8,376	5,447	
Goodwill	4,040	4,040	
Intangible assets, net of accumulated amortization	10,740	10,845	
Other assets	26		
Total assets	\$125,927	\$109,259	
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable	\$7,244	\$3,661	
Accrued compensation	12,997	11,523	
Accrued expenses	4,097	2,504	
Other current liabilities	14	716	
Total current liabilities	24,352	18,404	
Other liabilities	1,053	1,526	
Total liabilities	25,405	19,930	
Commitments and contingencies (Note 13)			
Stockholders' equity:			
Preferred stock; \$.001 par value; 5,000,000 shares authorized and 0 shares issued an	d		
outstanding	<del></del>		
Common stock; \$.001 par value; 150,000,000 shares authorized;			
109,467,416 issued and 109,040,869 outstanding at September 30, 2015 and	109	108	
108,776,247 issued and 107,789,611 outstanding at December 31, 2014			
Additional paid-in capital	156,074	162,433	
Treasury stock at cost:	(4.154	(5 627	`
426,547 shares at September 30, 2015 and 986,636 shares at December 31, 2014	(4,154)	(5,637	)
Accumulated deficit	(51,507)	(67,575	)
Total stockholders' equity	100,522	89,329	
Total liabilities and stockholders' equity	\$125,927	\$109,259	
See notes to condensed consolidated financial statements			

# MIMEDX GROUP, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share data) (unaudited)

	•		Nine Months Ended Septembe 30,		•			
	2015		2014		2015		2014	
Net sales	\$49,015		\$33,518		\$135,461		\$78,650	
Cost of sales	4,979		3,348		15,217		9,065	
Gross margin	44,036		30,170		120,244		69,585	
Operating expenses:								
Research and development expenses	2,187		2,014		6,072		5,204	
Selling, general and administrative expenses	34,901		24,193		96,860		61,238	
Amortization of intangible assets	234		232		699		695	
Operating income	6,714		3,731		16,613		2,448	
Other income (expense), net								
Interest income (expense), net	(5	)	(9	)	(18	)	(39	)
Income before income tax provision	6,709		3,722		16,595		2,409	
Income tax provision	(158	)	(22	)	(527	)	(22	)
Net income	\$6,551		\$3,700		\$16,068		\$2,387	
Net income per common share - basic	\$0.06		\$0.03		\$0.15		\$0.02	
Net income per common share - diluted	\$0.06		\$0.03		\$0.14		\$0.02	
Weighted average shares outstanding - basic	106,511,294		105,756,945		106,178,136		105,331,344	
Weighted average shares outstanding - diluted See notes to condensed consolidated financial sta	114,556,036 atements		112,814,658		114,110,120		112,525,016	

### MIMEDX GROUP, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (in thousands, except share data) (unaudited)

	Common Stoo	ck Issued		Treasury St	ock		
	Shares	Amount	Additional Paid - in Capital	Shares	Amount	Accumulated Deficit	Total
Balance December 31, 2014	108,776,247	\$108	\$162,433	986,636	\$(5,637	)\$(67,575	)\$89,329
Share-based compensation expense	_	_	12,564	_	_	_	12,564
Exercise of stock options	647,656	1	(6,560	)(1,098,071	) 10,024		3,465
Exercise of warrants	_				_		
Issuance of restricted stock	34,250		(12,804	)(1,765,859	) 12,804		
Restricted stock shares cancelled/forfeited	(2,058	)—	328	35,060	(328	)—	_
Shares issued for services performed	11,321	_	113	(5,172	)51	_	164
Stock repurchase		_	_	2,273,953	(21,068	)—	(21,068)
Net income	_	_			_	16,068	16,068
Balance September 30, 2015	109,467,416	\$109	\$156,074	426,547	\$(4,154	)\$(51,507	)\$100,522

See notes to condensed consolidated financial statements

## MIMEDX GROUP, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (in thousands) (unaudited)

	Nine Months Ended September 30,			
	2015		2014	
Cash flows from operating activities:				
Net income	\$16,068		\$2,387	
Adjustments to reconcile net income to net cash from operating activities:				
Depreciation	1,247		864	
Amortization of intangible assets	699		695	
Share-based compensation	12,564		8,161	
Increase (decrease) in cash resulting from changes in:				
Accounts receivable	(20,106	)	(7,212	)
Inventory	(520	)	(858	)
Prepaid expenses and other current assets	(1,201	)	(631	)
Other assets	(26	)	_	
Accounts payable	3,747		355	
Accrued compensation	1,474		3,859	
Accrued expenses	1,592		584	
Other liabilities	(1,087	)	312	
Net cash flows from operating activities	14,451		8,516	
Cash flows from investing activities:				
Purchases of equipment	(4,176	)	(1,830	)
Fixed maturity securities redemption	2,500			
Patent application costs	(594	)	(477	)
Net cash flows from investing activities	(2,270	)	(2,307	)
Cash flows from financing activities:				
Proceeds from exercise of stock options	3,465		1,497	
Proceeds from exercise of warrants			869	
Stock repurchase	(21,068	)	(5,312	)
Payments under capital lease obligations	(87	)	(89	)
Net cash flows from financing activities	(17,690	)	(3,035	)
Net change in cash	(5,509	)	3,174	
Cash and cash equivalents, beginning of period	46,582		44,078	
Cash and cash equivalents, end of period	\$41,073		\$47,252	
See notes to condensed consolidated financial statements				
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#### MIMEDX GROUP, INC.

## NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2015 AND 2014

#### 1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") from interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. Changes to GAAP are established by the Financial Accounting Standards Board ("FASB") in the form of Accounting Standards Updates ("ASU") to the FASB's Accounting Standards Codification ("ASC"). In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation of the results of operations for the periods presented have been included. Operating results for the nine months ended September 30, 2015 and 2014, are not necessarily indicative of the results that may be expected for the fiscal year. The balance sheet at December 31, 2014, has been derived from the audited consolidated financial statements at that date, but does not include all of the information and footnotes required by GAAP for complete financial statements.

You should read these condensed consolidated financial statements together with the historical consolidated financial statements of the Company for the year ended December 31, 2014, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014, filed with the SEC on March 13, 2015.

The Company operates in one business segment, Regenerative Biomaterials, which includes the design, manufacture, and marketing of products and tissue processing services for the Wound Care, Surgical, Sports Medicine, Ophthalmic and Dental market categories. The Company's biomaterial platform technologies include tissue technologies, AmnioFix® and EpiFix®, amniotic fluid derived allograft, OrthoFlo, and anticipated device technology, CollaFix<sup>TM</sup>, which the Company has yet to commercialize.

#### 2. Significant Accounting Policies

Please see Note 2 to the Company's Consolidated Financial Statements included in the Company's Form 10-K for the fiscal year ended December 31, 2014, for a description of all significant accounting policies.

#### Use of Estimates

The preparation of financial statements in conformity with 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 revenue and expenses during the reporting period. Actual results could differ from those estimates.

#### Accounts Receivable

Accounts receivable represent amounts due from customers for which revenue has been recognized. Generally, the Company does not require collateral or any other security to support its receivables.

The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses in the Company's existing receivables. The Company determines the allowance based on factors such as historical collection experience, customers' current creditworthiness, customer concentrations, age of accounts receivable balance and general economic conditions that may affect the customers' ability to pay.

#### Inventories

Inventory is valued at standard cost, which approximates actual cost computed on a first-in, first-out basis, not in excess of market value. The Company assesses the valuation of its inventory on a periodic basis and makes adjustments to the value for estimated excess and obsolete inventory based on estimates about future demand. The excess balance determined by this analysis becomes the basis for the Company's excess inventory charge. The Company's excess inventory review process includes analysis of sales forecasts, managing product rollovers and working with operations to maximize recovery of excess inventory.

#### Revenue Recognition

The Company sells its products through a combination of a direct sales force and independent stocking distributors and representatives in the U.S. and independent distributors in international markets. The Company recognizes revenue when title to the goods transfers to customers, provided there are no material remaining performance

obligations required of the Company or any matters of customer acceptance. In cases where the Company utilizes distributors or ships product directly to the end user, it recognizes revenue upon shipment provided all other revenue recognition criteria have been met. A portion of the Company's revenue is generated from inventory maintained at hospitals. For these products, revenue is recognized at the time

the product has been used or implanted. The Company records estimated sales returns, discounts and allowances as a reduction of net sales in the same period revenue is recognized.

#### Patent Costs

The Company incurs certain legal and related costs in connection with patent applications for tissue-based products and processes. The Company capitalizes such costs to be amortized over the expected life of the patent to the extent that an economic benefit is anticipated from the resulting patent or alternative future use is available to the Company and are included in Intangible Assets in the Condensed Consolidated Balance Sheets. The Company capitalized approximately \$594,000 of patent costs during the first nine months of 2015. The Company capitalized approximately \$477,000 of patent costs during the first nine months of 2014.

#### Treasury Stock

The Company accounts for the purchase of treasury stock under the cost method. Treasury stock which is reissued for the exercise of option grants and the issuance of restricted stock grants is accounted for on a first - in first - out (FIFO) basis.

#### Recent Accounting Pronouncements

The Company considers the applicability and impact of all ASUs issued effective and not yet effective. In May 2014, the Financial Accounting Standards Board issued ASU 2014-09, "Revenue Recognition - Revenue from Contracts with Customers" (ASU 2014-09) that requires companies to recognize revenue when a customer obtains control rather than when companies have transferred substantially all risks and rewards of a good or service. This update is effective for annual reporting periods beginning on or after December 15, 2017 and interim periods therein and requires expanded disclosures. The Company is currently assessing the impact the adoption of ASU 2014-09 will have on our condensed consolidated financial statements. All other ASUs issued effective and not yet effective for the nine months ended September 30, 2015, and through the date of this report, were assessed and determined to be either not applicable or are expected to have minimal impact on the Company's financial position or results of operations.

#### 3. Liquidity and Management's Plans

As of September 30, 2015, the Company had approximately \$41,073,000 of cash and cash equivalents. The Company reported total current assets of approximately \$102,745,000 and current liabilities of approximately \$24,352,000 as of September 30, 2015. The Company believes that its anticipated cash from operating and financing activities, and existing cash and cash equivalents will enable the Company to meet its operational liquidity needs and fund its planned investing activities for the next twelve months.

#### 4. Short Term Investments

Short term investments consist of approximately \$6,500,000 of FDIC insured certificates of deposit held with various financial institutions as of September 30, 2015. Short term investments consisted of approximately \$5,750,000 of FDIC insured certificates of deposit at December 31, 2014. The cost of these instruments approximates their fair market value at September 30, 2015 and December 31, 2014.

#### 5. Inventories

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

	September 30, 2015	December 31, 2014
Raw materials	\$376	\$255
Work in process	2,859	3,419
Finished goods	3,112	1,986
Inventory, gross	6,347	5,660
Reserve for obsolescence	(694	) (527
Inventory, net	\$5,653	\$5,133

#### 6. Investments

Investments consist of FDIC insured certificates of deposit with various U.S. financial institutions. As of December 31, 2014, the balance was approximately \$3,250,000, and the cost approximated fair market value.

#### 7. Property and Equipment

Property and equipment consist of the following as of September 30, 2015, and December 31, 2014 (in thousands):

	September 30,	December 31,	
	2015	2014	
Leasehold improvements	\$2,666	\$2,559	
Lab and clean room equipment	3,792	3,040	
Furniture and office equipment	3,789	2,398	
Construction in progress	2,556	949	
Property and equipment, gross	12,803	8,946	
Less accumulated depreciation	(4,427	) (3,499	)
Property and equipment, net	\$8,376	\$5,447	

Included in net property and equipment is approximately \$427,000 of equipment covered under capital leases. The corresponding liability of approximately \$163,000 is included in other liabilities in the accompanying Condensed Consolidated Balance Sheets. Interest rates for these leases range from approximately 3% to 12% with maturity dates from September 2016 to January 2018.

Also included is approximately \$1.0 million in leasehold improvements paid for by the landlord of the Company's main facility with a corresponding liability included in other liabilities which is amortized over the term of the lease. Depreciation expense for the nine months ended September 30, 2015 and 2014, was approximately \$1,247,000 and \$864,000, respectively, and approximately \$470,000 and \$313,000 for the three months ended September 30, 2015 and 2014, respectively.

#### 8. Intangible Assets and Royalty Agreement

Intangible assets are summarized as follows (in thousands):

Cost       Cost         Licenses (a) (b)       10 years       \$1,009         Patents & Know How (b)       14 years       7,941       7,891         Customer & Supplier Relationships (b)       14 years       3,761       3,761         Tradenames & Trademarks (b)       indefinite       1,008       1,008         In Process Research & Development (b)       n/a       25       25         Patents in Process (c)       n/a       1,627       1,083         Total       15,371       14,777         Less Accumulated amortization       (4,631       ) (3,932       )         Net       \$10,740       \$10,845		Weighted Average Amortization Lives	September 30, 2015	December 31, 2014
Patents & Know How (b)       14 years       7,941       7,891         Customer & Supplier Relationships (b)       14 years       3,761       3,761         Tradenames & Trademarks (b)       indefinite       1,008       1,008         In Process Research & Development (b)       n/a       25       25         Patents in Process (c)       n/a       1,627       1,083         Total       15,371       14,777         Less Accumulated amortization       (4,631       ) (3,932       )			Cost	Cost
Customer & Supplier Relationships (b)       14 years       3,761       3,761         Tradenames & Trademarks (b)       indefinite       1,008       1,008         In Process Research & Development (b)       n/a       25       25         Patents in Process (c)       n/a       1,627       1,083         Total       15,371       14,777         Less Accumulated amortization       (4,631       ) (3,932       )	Licenses (a) (b)	10 years	\$1,009	\$1,009
Tradenames & Trademarks (b)       indefinite       1,008       1,008         In Process Research & Development (b)       n/a       25       25         Patents in Process (c)       n/a       1,627       1,083         Total       15,371       14,777         Less Accumulated amortization       (4,631       ) (3,932       )	Patents & Know How (b)	14 years	7,941	7,891
In Process Research & Development (b)       n/a       25       25         Patents in Process (c)       n/a       1,627       1,083         Total       15,371       14,777         Less Accumulated amortization       (4,631       ) (3,932       )	Customer & Supplier Relationships (b)	14 years	3,761	3,761
Patents in Process (c)       n/a       1,627       1,083         Total       15,371       14,777         Less Accumulated amortization       (4,631       ) (3,932       )	Tradenames & Trademarks (b)	indefinite	1,008	1,008
Total 15,371 14,777 Less Accumulated amortization (4,631 ) (3,932 )	In Process Research & Development (b)	n/a	25	25
Less Accumulated amortization (4,631 ) (3,932 )	Patents in Process (c)	n/a	1,627	1,083
	Total		15,371	14,777
Net \$10,740 \$10,845	Less Accumulated amortization		(4,631	) (3,932
	Net		\$10,740	\$10,845

On January 29, 2007, the Company acquired a license from Shriners Hospitals for Children and University of South Florida Research Foundation, Inc. in the amount of \$996,000. Within 30 days after the receipt by the Company of approval by the FDA allowing the sale of the first licensed product, the Company is required to pay an (a) additional \$200,000 to the licensor. Due to its contingent nature, this amount is not recorded as a liability. The Company will also be required to pay a royalty of 3% on all commercial sales revenue from the licensed products. The Company is also obligated to pay a \$50,000 minimum annual royalty payment over the life of the license. As of September 30, 2015, this license had a remaining net book value of approximately \$134,000.

- On January 5, 2011, the Company acquired Surgical Biologics, LLC. As a result, the Company recorded intangible assets for Customer & Supplier Relationships of \$3,761,000, Patents & Know-How of \$7,690,000,
- (b) Licenses of \$13,000, Trade Names & Trademarks of \$1,008,000 and In-Process Research & Development of \$25,000. For the nine months ended September 30, 2015, approximately \$50,000 of costs associated with patents granted during the period were capitalized and included in Patents & Know-How subject to amortization. Patents in Process consist of capitalized external legal and other registration costs in connection with internally
- (c) developed tissue-based patents that are pending. Once issued, the costs associated with a given patent will be included in Patents & Know-How under intangible assets subject to amortization.

Amortization expense for the nine months ended September 30, 2015 and 2014, was approximately \$699,000 and \$695,000, respectively and \$234,000 and \$232,000 for three months ended September 30, 2015 and 2014, respectively.

Expected future amortization of intangible assets as of September 30, 2015, is as follows (in thousands):

	Estimated
Year ending December 31,	Amortization
	Expense
2015 (a)	\$233
2016	932
2017	843
2018	833
2019	833
Thereafter	6,058
	\$9,732

(a) Estimated amortization expense for the year ending December 31, 2015, includes only amortization to be recorded after September 30, 2015.

#### 9. Net Income Per Share

Basic net income per common share is computed using the weighted-average number of common shares outstanding during the period. Diluted net income per common share is computed using the weighted-average number of common and dilutive common equivalent shares from stock options, restricted stock, and warrants using the treasury stock method.

The following table sets forth the computation of basic and diluted net income per share (in thousands except share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net income	\$6,551	\$3,700	\$16,068	\$2,387
Denominator for basic earnings per share - weighted average shares	106,511,294	105,756,945	106,178,136	105,331,344
Effect of dilutive securities: Stock options, restricted stock, and warrants outstanding(a)	8,044,742	7,057,713	7,931,984	7,193,672
Denominator for diluted earnings per share - weighted average shares adjusted for dilutive securities	114,556,036	112,814,658	114,110,120	112,525,016
Income per common share - basic	\$0.06	\$0.03	\$0.15	\$0.02
Income per common share - diluted	\$0.06	\$0.03	\$0.14	\$0.02

(a) Securities outstanding that are included in the computation above, utilizing the treasury stock method are as follows:

	Three Months	Three Months	Nine Months	Nine Months
	Ended	Ended	Ended	Ended
	September 30,	September 30,	September 30,	September 30,
	2015	2014	2015	2014
Outstanding Stock Options	7,320,155	6,651,994	7,366,426	6,752,310
Outstanding Warrants	38,023	194,002	37,820	275,593
Restricted Stock Awards	686,564	211,717	527,738	165,769
	8,044,742	7,057,713	7,931,984	7,193,672

#### 10. Equity

**Stock Incentive Plans** 

The Company has three share-based compensation plans: the MiMedx Group, Inc. Assumed 2006 Stock Incentive Plan (the "Assumed 2006 Plan"), the MiMedx Inc. 2007 Assumed Stock Plan (the "Assumed 2007 Plan") and the MiMedx Group Inc. Amended and Restated Assumed 2005 Stock Plan (the "Assumed 2005 Plan") which provide for the granting of qualified incentive and non-qualified stock options, stock appreciation awards and restricted stock awards to employees, directors, consultants and advisors. The awards are subject to a vesting schedule as set forth in each individual agreement. The Company intends to use only the Assumed 2006 Plan to make future grants. The number of assumed options under the Assumed 2005 Plan and Assumed 2007 Plan outstanding at September 30, 2015 totaled 195,000. The maximum number of shares of common stock that can be issued under the Assumed 2006 Plan is 26,500,000 at September 30, 2015.

During the nine months ended September 30, 2015, 5,172 shares of common stock valued at approximately \$57,000 were issued under the Assumed 2006 Plan to a consultant in return for services performed. Activity with respect to the stock options is summarized as follows:

Waishead Assaussa

	Number of Shares	Average Exercise Price	Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2015	16,474,227	\$3.43		
Granted	75,100	\$9.66		
Exercised	(1,745,727)	\$1.97		
Unvested options forfeited	(175,900 )	\$6.62		
Vested options expired	(52,331)	\$1.89		
Outstanding at September 30, 2015	14,575,369	\$3.60	6.7	\$88,305,987
Vested at September 30, 2015	10,919,348	\$2.70	6.2	\$75,897,265
Vested or expected to vest at September 30, 2015	(a) 14,455,019	\$3.57	6.7	\$87,979,308
(a) Includes forfeiture adjusted unvested shares.				

The intrinsic value of the options exercised during the nine months ended September 30, 2015, was approximately \$14,400,192.

Following is a summary	of stock ontice	ns outstanding a	ind exercisable at S	September 30, 2015.
I offowing is a suffiffial	or stock opin	ns outstanding a	ma exercisable at t	) C p t C 1110 C 1 3 0 , 2 0 1 3 .

	Options Outstanding			Options Exercisable	
		Weighted-Average	Weighted-		Weighted-
Dange of Evening Driess	Number	Remaining	Average	Number	Average
Range of Exercise Prices	outstanding	Contractual Term	Exercise	Exercisable	Exercise
		(in years)	Price		Price
\$0.50 - \$0.76	441,429	3.6	\$0.72	441,429	\$0.72
\$0.87 - \$1.35	4,951,055	5.9	1.19	4,951,055	1.19
\$1.40 - \$2.45	1,810,868	5.0	1.92	1,810,868	1.92
\$2.66 - \$3.99	1,021,621	7.1	3.05	679,274	2.99
\$4.19 - \$6.38	3,642,206	7.6	5.35	2,153,519	5.31
\$6.45 - \$9.78	2,579,690	8.4	7.29	883,203	7.14
\$9.90- \$10.99	128,500	9.2	10.47		
	14,575,369	6.7	\$3.60	10,919,348	\$2.70

Total unrecognized compensation expense related to granted stock options at September 30, 2015, was approximately \$8,325,684 and will be charged to expense ratably through May 2018.

The fair value of options granted by the Company is estimated on the date of grant using the Black-Scholes-Merton option-pricing model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. Expected volatilities are based on historical volatility of peer companies and other factors estimated over the expected term of the options. The term of employee options granted is derived using the "simplified method," which computes expected term as the mid point between the weighted average time to vesting and the contractual maturity. The simplified method was used due to the Company's lack of sufficient historical data to provide a reasonable basis upon which to estimate the expected term due to the limited period of time its equity shares have been publicly traded. The term for non-employee options is generally based upon the contractual term of the option. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the period of the expected term or contractual term as described.

The assumptions used in calculating the fair value of options using the Black-Scholes-Merton option-pricing model are set forth in the following table:

	Nine Months Ended September 30,		
	2015	2014	
Expected volatility	54.4 - 58.1%	63.6 - 64.5%	
Expected life (in years)	6.0	6.0	
Expected dividend yield	<del></del>	_	
Risk-free interest rate	1.51% - 1.68%	1.69% - 1.96%	

The weighted-average grant date fair value for options granted during the nine months ended September 30, 2015, was approximately \$5.15.

#### Restricted Stock Awards

Activity with respect to restricted stock awards is summarized as follows:

	Number	Weighted-Average
	of	Grant Date
	Shares	Fair Value
Unvested at January 1, 2015	1,228,898	\$7.16
Granted	1,800,109	9.85
Vested	(375,193	) 6.47
Forfeited	(37,118	) 9.67
Unvested at September 30, 2015	2,616,696	\$9.08

As of September 30, 2015, there was approximately \$17,720,236 of total unrecognized stock-based compensation related to time-based, nonvested restricted stock. That expense is expected to be recognized on a straight-line basis

over a weighted-

average period of 2.2 years, which approximates the remaining vesting period of these grants. All shares noted above as unvested are considered issued and outstanding at September 30, 2015.

For the three and nine months ended September 30, 2015 and 2014, the Company recognized stock-based compensation as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Cost of sales	\$85	\$70	\$270	\$243
Research and development	202	170	591	493
Selling, general and administrative	4,091	2,781	11,703	7,425
	\$4,378	\$3,021	\$12,564	\$8,161

#### Warrants

As of September 30, 2015, the Company had 42,400 common stock warrants outstanding with an exercise price of \$1.09 representing compensation to consultants and advisors in connection with previous debt offerings. The warrants expire in December 2016 and are classified as equity.

#### Treasury Stock

On May 12, 2014, the Company announced that its Board of Directors had authorized the repurchase of up to \$10,000,000 of its common stock from time to time, through December 31, 2014. On December 12, 2014, the Board extended this program until December 31, 2015. On January 5, 2015, the Board increased the authorization under the program to \$20,000,000, and on April 27, 2015 the Board increased the authorization from \$20,000,000 to \$30,000,000. The timing and amount of future repurchases, if any, will depend upon the Company's stock price, economic and market conditions, regulatory requirements, and other corporate considerations. The Company may initiate, suspend or discontinue purchases under the stock repurchase program at any time.

For the nine months ended September 30, 2015, the Company purchased approximately 2,273,953 shares of its common stock for a purchase price of approximately \$21,002,000, before brokerage commissions of approximately \$66,000 bringing the total amount spent under the program to approximately \$26,585,000 since inception. As of September 30, 2015, the Company had approximately \$3,415,000 remaining under the repurchase program. Additionally, for the nine months ended September 30, 2015, the Company reissued 2,834,042 shares from the Treasury for common and restricted stock grants and stock option exercises, net of forfeitures, with an aggregate carrying value of approximately \$22,551,000.

#### 11. Income taxes

The effective tax rates for continuing operations of 3.2% and 0.90% for the nine months ended September 30, 2015 and September 30, 2014, respectively, were determined using an estimated annual effective tax rate and after considering any discrete items for such periods. Due to a valuation allowance against the Company's U.S. deferred tax assets, the effective tax rate for the nine months ended September 30, 2015, does not include the expense of the current period U.S. taxable income. A valuation allowance is recorded to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that a portion or none of the deferred tax assets will be realized. After consideration of all the evidence, including reversal of deferred tax liabilities, future taxable income and other factors, management has determined that a full valuation allowance is necessary as of September 30, 2015. As a result, income tax expense for the nine months ended September 30, 2015, is primarily due to income tax expense in certain state jurisdictions.

As a result of anticipated profitability for the year and positive trends in the foreseeable future, the Company may release all or a portion of this valuation allowance by the end of 2015. However, the exact timing and amount of the valuation allowance released are subject to change based on the level of profitability that the Company is able to actually achieve for the year and its visibility into future period results. The potential release of this valuation allowance during 2015 would have a material impact on the Company's recorded tax expense (benefit) in the period of

reversal. The Company expects to release this valuation allowance when management determines that it is more likely than not that a portion or all of its deferred tax asset will be realized.

#### 12. Supplemental disclosure of cash flow and non-cash investing and financing activities:

Selected cash payments, receipts, and noncash activities are as follows (in thousands):

	Nine Months Ended Septemb		ber
	30,		
	2015	2014	
Cash paid for interest, net	\$18	\$38	
Income taxes paid	1,506	81	
Stock issuance of 16,493 and 13,158 shares in exchange for services performed, respectively	164	86	
Retirement of fixed assets	319	_	

#### 13. Contractual Commitments and Contingencies

#### **Contractual Commitments**

In addition to the Capital Leases noted above in Note 7, the Company has entered into operating lease agreements for facility space and equipment. These leases expire over the next five years and generally contain renewal options. The Company anticipates that most of these leases will be renewed or replaced upon expiration. The Company also has commitments for meeting space and to various charitable organizations. The estimated annual lease payments, meeting space and charitable organization commitments are as follows (in thousands):

#### 12-month period ended September 30

2016	\$2,574
2017	2,327
2018	1,792
2019	817
Thereafter	319
	\$7,829

Rent expense for the nine months ended September 30, 2015 and 2014, was approximately \$956,000 and \$847,000, respectively, and was approximately \$363,000 and \$282,000 for three months ended September 30, 2015 and 2014, respectively, and is allocated among cost of sales, research and development, and selling, general and administrative expenses.

#### Letters of Credit

As a condition of the lease for the Company's main facility, the Company is obligated under standby letters of credit in the amount of approximately \$235,000. These obligations are reduced at various times over the life of the lease.

FDA Untitled Letter, Draft Guidance and Related Litigation

#### FDA Untitled Letter

Initially, MiMedx processed its tissue allografts in only one form, which was a sheet form. In 2011, MiMedx introduced a micronized form of its sheet allografts.

The FDA has specific regulations governing human cells, tissues and cellular and tissue-based products, or HCT/Ps. An HCT/P is a product containing or consisting of human cells or tissue intended for transplantation into a human patient. If an HCT/P meets the criteria for regulation solely under Section 361 of the Public Health Service Act (so-called "361 HCT/Ps"), no FDA review for safety and effectiveness under a drug, device, or biological product marketing application is required.

MiMedx believes that all of its tissue products qualify as 361 HCT/Ps. On August 28, 2013, however, the FDA issued an Untitled Letter alleging that one type of the Company's products, its micronized allografts, do not meet the criteria for regulation solely under Section 361 of the Public Health Service Act and that, as a result, MiMedx would need a biologics license to lawfully market those micronized products.

In November 2013, the FDA clarified the basis for its position regarding the micronized products. Specifically, the FDA explained its belief that "[c]ryo-milling cut, dehydrated amniotic/chorionic membrane results in a micron-sized powder and the loss of the tensile strength and elasticity that are essential characteristics of the original amniotic/chorionic tissue relating to its utility to function as a 'physical membrane' (i.e. covering, barrier)." The Company responded to the FDA that while it does not agree with the FDA's position, it understands the FDA's interest in further regulating this emerging technology. Accordingly, the Company proposed to the FDA that it would pursue the Investigational New Drug ("IND") and Biologics License Application ("BLA") process for certain micronized products, and, in parallel, also proposed to enter into negotiations with the FDA on a plan to transition the micronized products to licensed biological products and continue to market the micronized products under specific conditions. On July 22, 2014, the Company filed its first IND application with the FDA. The application was allowed, paving the way for a Phase IIB clinical trial of its micronized product for a specified indication of use in anticipation of a BLA, which the Company expects to submit at a future date. The clinical trial is expected to enroll approximately 150 patients in 10 - 20 clinical sites in the U.S. The Company initiated the trial in March of 2015.

The Company also requested a transition agreement to allow it to continue to market its current micronized products for certain specified uses while pursuing one or more BLAs. The FDA continues to assert that the current form of the Company's micronized products are more than minimally manipulated and therefore are not eligible for marketing solely under Section 361 of the Public Health Service Act. The Company has conducted tests and has engaged independent laboratories to conduct tests that confirm that tensile strength and modulus of elasticity are not diminished by the process used by the Company to create its micronized products.

If the FDA does allow the Company to continue to market a micronized form of its sheet allografts, it may impose conditions, such as labeling restrictions and compliance with Current Good Manufacturing Practices ("cGMP"). It is also possible that the FDA will not allow the Company to market any form of a micronized product without a biologics license and could even require the Company to recall its micronized products. Revenues from micronized products comprised approximately 14% of the Company's revenues in 2014.

#### **Draft Guidance on Minimal Manipulation**

On December 22, 2014, the FDA issued for comment "Draft Guidance for Industry and FDA Staff: Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products." Essentially the Draft Guidance takes the same position with respect to micronized amniotic tissue that it took in the Untitled Letter to MiMedx 16 months earlier.

The period for submitting comments on the Draft Guidance expired on February 23, 2015. The Company has submitted comments to the Draft Guidance asserting that the Draft Guidance represents agency action that goes far beyond the FDA's statutory authority, is inconsistent with existing HCT/P regulations and the FDA's prior positions, and is internally inconsistent and scientifically unsound. Additionally, the Company asked the FDA to allow MiMedx to continue to market its micronized products until the guidance or regulations, as the case may be, have been fully vetted through a process of notice and comment rule making.

If the FDA does allow the Company to continue to market a micronized form of its sheet allografts either prior to or after finalization of the Draft Guidance, it may impose conditions, such as labeling restrictions and compliance with Current Good Manufacturing Practices ("cGMP"). It is also possible that the FDA will not allow the Company to market any form of a micronized product without a biologics license even prior to finalization of the Draft Guidance and could even require the Company to recall its micronized products. Revenues from micronized products comprised approximately 14% of the Company's revenues in 2014.

#### Related Litigation

Following the publication of the Untitled Letter from the FDA regarding the Company's micronized products in September 2013, the trading price of the Company's stock dropped sharply and several purported class action lawsuits were filed against the Company and certain of its executive officers asserting violations of the Securities Act of 1933 and the Securities Exchange Act of 1934 with respect to various statements and alleged omissions related to the Company's belief that its products were 361 HCT/Ps, including its micronized products. These cases have now all been removed to, and consolidated in, the United States District Court for the Northern District of Georgia. By order dated December 9, 2013, the Court approved the appointment of a lead plaintiff and a lead counsel. A Consolidated Amended Class Action Complaint, containing substantially the same causes of action and claims for relief as the initial complaints, was filed on January 27, 2014. The plaintiffs filed a motion to certify the proposed class on March 16, 2015, which defendants opposed on May 15, 2015, while also moving to exclude plaintiffs'

expert. No ruling on either motion has been issued and the case is currently in the discovery phase. The Company currently believes that the outcome of this litigation will not have a material adverse impact on the Company's financial position or results of operations.

Draft Guidance on Homologous Use and Announcement of Public Hearing

On October 28, 2015, the FDA issued for comment, "Draft Guidance for Industry and FDA Staff: Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products". The Company is currently evaluating this Homologous Use draft guidance and expects to submit comments prior to the deadline. The FDA has also indicated that it will hold a public hearing on April 13, 2016 to obtain input on the Homologous Use draft guidance and the previously released Minimal Manipulation draft guidance, as well as other recently issued guidance documents on HCT/Ps.

#### OIG Subpoena

In the fourth quarter of 2014, the Company received a subpoena from the Office of Inspector General, U.S. Department of Health and Human Services, or OIG, in connection with a civil investigation into matters primarily related to the Company's sales and marketing activities. In March 2015, the Company received notice from the Department of Justice that it declined at that time to intervene in the qui tam action that gave rise to the issuance of the subpoena. The qui tam plaintiff had 120 days from the date of the Department of Justice's notice to proceed with the case. The 120 day period passed without initiation of the lawsuit. The plaintiff, who is an executive at Company's competitor Organogenesis, Inc., voluntarily dismissed the lawsuit in July 2015. This dismissal was approved by the Court on October 6, 2015.

#### Patent Litigation

On April 22, 2014, the Company filed a patent infringement lawsuit against Liventa Bioscience, Inc. ("Liventa"), Medline Industries, Inc. ("Medline") and Musculoskeletal Transplant Foundation, Inc. ("MTF") for permanent injunctive relief and unspecified damages. In addition to the allegations of infringement of MiMedx's patents, the lawsuit asserts that Liventa and Medline knowingly and willfully made false and misleading representations about their respective products to providers, patients, and in some cases, prospective investors (the "Liventa Action"). The Liventa Action was filed in the United States District Court for the Northern District of Georgia.

MiMedx asserts that Liventa (formerly known as AFCell Medical, Inc.), Medline and MTF infringed and continue to infringe certain of the Company's patents relating to the MiMedx dehydrated human amnion/chorion membrane ("dHACM") allografts. MTF is the tissue processor while Liventa and Medline are the distributors of the allegedly infringing products. On May 30, 2014, defendants filed answers to the Complaint, denying the allegations in the Complaint. They also raised affirmative defenses of non-infringement, invalidity, laches and estoppel. MTF and Medline also filed counterclaims seeking declaratory judgments of non-infringement and invalidity. With the parties close to ending document discovery, fact depositions are currently being scheduled. Meanwhile, claim construction briefing is complete and the parties await the Court's guidance on a date for the Markman hearing. In patent litigation, a Markman hearing is also called a claim construction hearing, in which a judge decides what the language of a patent means as a matter of law.

On May 16, 2014, the Company also filed a patent infringement lawsuit against Transplant Technology, Inc. d/b/a Bone Bank Allografts ("Bone Bank") and Texas Human Biologics, Ltd. ("Biologics") for permanent injunctive relief and unspecified damages (the "Bone Bank Action"). The Bone Bank Action was filed in the United States District Court for the Western District of Texas. This lawsuit similarly asserts that Bone Bank and Biologics infringed certain of the Company's patents through the manufacturing and sale of their placental-derived tissue graft products. On July 10, 2014, defendants filed an answer to the Complaint, denying the allegations in the Complaint. They also raised affirmative defenses of non-infringement and invalidity and filed counterclaims seeking declaratory judgments of non-infringement and invalidity. The Bone Bank Action is in an advanced stage. The parties have (i) substantially completed document production; (ii) taken several fact depositions (both party and non-party); and (iii) completed claim construction briefing. The Markman hearing in this case was held on October 2, 2015.

In addition to defending the claims in the pending district court litigations, defendants in each case have challenged certain of the Company's patents in several inter-partes review proceedings to avoid the high burden of proof of proving invalidity by "clear and convincing evidence" in the district court litigations. An inter partes review (or "IPR") is a request for a specialized group within the United States Patent and Trademark Office to review the validity of a plaintiff's patent claims. The defendants in the Bone Bank Action have challenged the validity of the Company's 8,597,687 and 8,709,494 patents (the "'687" and "'494" patents, respectively); while the defendants in the Liventa Action have challenged the validity of the Company's 8,372,437 and 8,323,701 patents (the "'437" and "'701" patents, respectively). On June 29, 2015, the Patent Trial and Appeals Board ("PTAB") denied defendants' request for institution of an IPR with respect to the '494 patent on all seven challenged grounds. On August 18, 2005, the PTAB also denied defendants' request for institution of an IPR with respect to the '701

patent on all six challenged grounds. That is, the PTAB decided in each case that the defendants failed to establish a reasonable likelihood that defendants would prevail in showing any of the challenged claims of the '494 or the '701 patent were unpatentable. On July 10, 2015 the PTAB issued an opinion allowing a review of the '687 patent to proceed, although on only two of the five challenged grounds. The PTAB also adopted MiMedx's construction of the claims which will govern the Board's review of the '687 patent. On August 18, 2015, the PTAB issued an opinion allowing a review of the '437 patent to proceed, although only on one of the seven challenged grounds.

Following the PTAB decisions, the defendants in the Bone Bank Action moved to stay the district court litigation, despite the Court's previous denial of such a stay, pending the outcome of the '687 patent inter partes review. The parties agreed to stay the case with respect to the '687 patent only and the Court denied Bone Bank's motion to stay the litigation with respect to the '494 patent. The Company has also successfully defeated an attempt by defendants in the Liventa Action to stay that litigation -- also pending the outcome of the inter-partes review of the patents at issue in that case.

Finally, on March 2, 2015, the Company filed a patent infringement lawsuit against NuTech Medical, Inc. ("NuTech") and DCI Donor Services, Inc. ("DCI") for permanent injunctive relief and unspecified damages. This lawsuit was filed in the United States District Court for the Northern District of Alabama. The lawsuit alleges that NuTech and DCI have infringed and continue to infringe the Company's patents through the manufacture, use, sale, and/or offering of their tissue graft product. The lawsuit also asserts that NuTech knowingly and willfully made false and misleading representations about its products to customers and/or prospective customers. On April 17, 2015, NuTech filed a motion to dismiss the case purportedly for lack of patentable subject matter, which the Company has opposed. NuTech also filed a motion to stay the case pending disposition of the motion to dismiss, which MiMedx also opposed, and on which the Court declined to rule. Hearing on the motion to dismiss occurred on August 20, 2015; no ruling on the motion to dismiss has yet been issued.

#### 14. Subsequent Events

On October 12, 2015, the Company and its subsidiaries entered into a Credit Agreement (the "Credit Agreement") with certain lenders and Bank of America, N.A., as administrative agent. The Credit Agreement establishes a senior secured revolving credit facility in favor of the Company with a maturity date of October 12, 2018 and an aggregate lender commitment of up to \$50 million. The Credit Agreement also provides for an uncommitted incremental facility of up to \$35 million, which can be exercised as one or more revolving commitment increases or new term loans, all subject to certain customary terms and conditions set forth in the Credit Agreement. Borrowings under the facility will bear interest at LIBOR plus 1.5% to 2.25%. Fees paid in connection with the initiation of the credit facility totaled approximately \$400,000. The Credit Agreement contains customary representations, warranties, covenants, and events of default. As of the filing of this Form 10-Q, there are no outstanding revolving loans under the credit facility.

During October 2015, the Board of Directors increased the authorization under the share repurchase program detailed in Note 10 from \$30,000,000 to \$50,000,000.

## Schedule II Valuation and Qualifying Accounts MIMEDX GROUP, INC. AND SUBSIDIARIES SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS

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Three and Nine Months Ended September 30, 2015 and 2014 (in thousands)

	Balance at Beginning of Period	Additions charged to Expense or Revenue	Deductions and write-offs	Balance at End of Period
For the three months ended September 30,				
2015				
Allowance for doubtful accounts	\$2,504	\$800	\$(172	)\$3,132
Allowance for product returns	1,030	906	(407	) 1,529
Allowance for obsolescence	553	227	(87	)693
For the three months ended September 30, 2014				
Allowance for doubtful accounts	\$678	\$523	<b>\$</b> —	\$1,201
Allowance for product returns	270	806	(399	)677
Allowance for obsolescence	352	76	(3)	)425
For the nine months ended September 30, 2015				
Allowance for doubtful accounts	\$1,750	\$1,560	\$(178	)\$3,132
Allowance for product returns	841	2,349	(1,661	) 1,529
Allowance for obsolescence	527	447	(281	)693
For the nine months ended September 30,				
2014				
Allowance for doubtful accounts	\$407	\$808	\$(14	) \$ 1,201
Allowance for product returns	215	1,419	(957	)677
Allowance for obsolescence	322	140	(37	)425

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations Overview

MiMedx® is an integrated developer, processor and marketer of patent protected and proprietary regenerative biomaterial products and bioimplants processed from human amniotic membrane and other birth tissues. "Innovations in Regenerative Biomaterials" is the framework behind our mission to give physicians products and tissues to help the body heal itself. Our biomaterial platform technologies are AmnioFix®, EpiFix®, CollaFix<sup>TM</sup> and OrthoFlo. AmnioFix and EpiFix are our tissue technologies processed from human amniotic membrane derived from donated placentas. Through our donor program, a mother delivering via scheduled full-term Caesarean section birth can elect in advance of delivery to donate the placenta in lieu of having it discarded as medical waste. We process the human amniotic membrane utilizing our proprietary PURION® Process, to produce a safe and effective implant. MiMedx is the leading supplier of amniotic tissue, having supplied over 500,000 allografts to date for application in the Wound Care, Surgical, Orthopedic, Spine, Sports Medicine, Ophthalmic and Dental sectors of healthcare. The Company has recently introduced OrthoFlo, an amniotic fluid derived allograft. Amniotic fluid is donated by consenting mothers delivering healthy babies by scheduled full-term Cesarean section births. CollaFix<sup>TM</sup>, our next technology platform we plan to commercialize, is our collagen fiber technology, developed with our patented cross-linking polymers, designed to mimic the natural composition, structure and mechanical properties of musculoskeletal tissues in order to augment their repair. CollaFix<sup>TM</sup> is the only biological, biodegradable, biomimetic technology that matches human tendon in strength and stiffness.

Draft FDA Guidance

On December 22, 2014, the FDA issued for comment "Draft Guidance for Industry and FDA Staff: Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products." Essentially, the Draft Guidance takes the same position with respect to micronized amniotic tissue that it took in the Untitled Letter to the Company 16 months earlier. The period for submitting comments on the Draft Guidance expired on February 23, 2015. The Company has submitted comments to the Draft Guidance asserting that the Draft Guidance represents agency action that goes far beyond the FDA's statutory authority, is inconsistent with existing HCT/ P regulations and the FDA's prior positions, and is internally inconsistent and scientifically unsound. Additionally, the Company asked the FDA to allow MiMedx to continue to market its micronized products until the guidance or regulations, as the case may be, have been fully vetted through a process of notice and comment rule making. The Draft Guidance document evoked wide-ranging commentary from industry, many of which were similar to the Company's comments.

On October 28, 2015, the FDA issued for comment, "Draft Guidance for Industry and FDA Staff: Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products". The Company is currently evaluating this Homologous Use draft guidance and expects to submit comments prior to the deadline. The FDA has also indicated that it will hold a public hearing on April 13, 2016 to obtain input on the Homologous Use draft guidance and the Minimal Manipulation draft guidance, as well as other recently issued guidance documents on HCT/Ps.

The FDA's recent actions in regards to using draft guidance documents to effect change without notice and comment rulemaking have garnered the attention of Congress and industry. In May 2014, Senators Lamar Alexander, Richard Burr, Orrin Hatch, and Johnny Isaakson wrote to then-FDA Commissioner Margaret Hamburg expressing concern over the use of draft guidances to make substantive policy changes. One noted concern was that draft guidances are not being revised, finalized, or withdrawn in a timely manner, leaving the FDA-regulated entities without certainty as to what the FDA's expectations are. The Senators further remarked that "FDA issues guidance that seemingly does not take into account, or may even conflict with, the scientific community." May 6, 2014 Letter to Commissioner Hamburg at page 2. On January 29, 2015, Senator Lamar Alexander and Senator Richard Burr jointly released their report, "Innovation for Healthier Americans: Identifying Opportunities for Meaningful Reform to Our Nation's Medical Product Discovery and Development," in which they express concern that the current FDA framework is stifling medical innovation and depriving patients of cutting-edge medical treatment. The report notes "[t]he disparity between

the pace of scientific discovery and development outside of the FDA and the pace of growth in the FDA's scientific knowledge threatens America's position as a global leader in medical innovation." Report at page 7. In addition, the House Energy and Commerce Committee's Subcommittee on Oversight and Investigations has initiated an inquiry into the FDA's practices related to issuance of Untitled Letters and use of Guidance Documents to change rules and policies. The practices being investigated by the House Subcommittee are similar to those experienced by the Company in relation to its 2013 Untitled Letter concerning its micronized product line.

Results of Operations Comparison for the Three Months Ended September 30, 2015, to the Three Months Ended September 30, 2014

Revenue

Total revenue increased approximately \$15.5 million, or 46%, to \$49.0 million for the three months ended September 30, 2015, as compared to \$33.5 million for the three months ended September 30, 2014. The increase in revenue as compared to the prior year is due to increased wound care sales and surgical sales in both commercial and government accounts.

Tissue Processing Costs and Cost of Products Sold

Cost of products sold as a percentage of revenue was virtually unchanged at 10.2 % as compared to 10.0% in the prior year.

Research and Development Expenses

The Company's research and development expenses ("R&D expenses") increased approximately \$0.2 million, or 9%, to \$2.2 million during the three months ended September 30, 2015, compared to approximately \$2.0 million in the prior year. The increase is primarily related to increased investments in scientific studies, clinical trials and personnel costs.

R&D expenses consist primarily of internal personnel costs, expenses of clinical trials, fees paid to external consultants, and the cost of supplies and instruments used in the Company's laboratories.

Selling, General and Administrative Expenses

Selling, General and Administrative expenses for the three months ended September 30, 2015, increased approximately \$10.7 million to \$34.9 million compared to \$24.2 million for the three months ended September 30, 2014. Selling expense increases were driven by costs associated with expanding the Company's direct sales organization, increased commissions due to higher sales volume and an increase in share-based compensation. Additional spending increases included support costs related to medical reimbursement, accounting, information technology infrastructure to help manage the growth of the business, and legal costs due to patent litigation. Selling, General and Administrative expenses consist of personnel costs, professional fees, sales commissions, sales training costs, industry trade show fees and expenses, product promotion and product literature costs, facilities costs and other sales, marketing and administrative costs, depreciation and amortization, and share-based compensation.

Results of Operations Comparison for the Nine Months Ended September 30, 2015, to the Nine Months Ended September 30, 2014

Revenue

Total revenue increased approximately \$56.8 million, or 72%, to \$135.5 million for the nine months ended September 30, 2015, as compared to \$78.7 million for the nine months ended September 30, 2014. The increase in revenue as compared to the prior year is due to increased wound care sales and surgical sales in both commercial and government accounts.

Tissue Processing Costs and Cost of Products Sold

Cost of products sold as a percentage of revenue improved slightly to 11.2% from 11.5% in the prior year. The improvement was due primarily to the increase in direct sales revenue, improved product mix and higher production rates that absorb a greater percentage of fixed manufacturing costs.

#### Research and Development Expenses

The Company's R&D expenses increased approximately \$0.9 million, or 17%, to \$6.1 million during the nine months ended September 30, 2015, compared to approximately \$5.2 million in the prior year. The increase is primarily related to increased investments in clinical trials and personnel costs.

#### Selling, General and Administrative Expenses

Selling, General and Administrative expenses for the nine months ended September 30, 2015, increased approximately \$35.6 million to \$96.9 million compared to \$61.2 million for the nine months ended September 30, 2014. Selling expense increases were driven by costs associated with building a direct sales organization, and increased commissions due to higher sales volume. Additional spending increases included spending on support costs related to medical reimbursement, including the Company's reimbursement hotline; information technology infrastructure to help manage the growth of the business; and increased share-based compensation expense.

#### Liquidity and Capital Resources

Revenue continues to increase quarter - over - quarter while management strives to maintain tight controls over spending. As of September 30, 2015, the Company had approximately \$41.1 million of cash and cash equivalents. The Company reported total current assets of approximately \$102.7 million and total current liabilities of approximately \$24.4 million at September 30, 2015, which represents a current ratio of 4.2 as of September 30, 2015. Management believes that its anticipated cash from operating and financing activities and existing cash and cash equivalents, will enable the Company to meet its operational liquidity needs and fund its planned investing activities for the next year. In addition, as previously announced, on October 12, 2015, the Company entered into a new three-year \$50 million senior secured revolving credit facility, which provides additional liquidity.

For the nine months ended September 30, 2015, the Company purchased approximately 2,273,953 shares of its common stock for a purchase price of approximately \$21,002,000, before brokerage commissions of approximately \$66,000 bringing the total amount spent under the program to approximately \$26,585,000 since inception. As of September 30, 2015, the Company had approximately \$3,415,000 remaining under the repurchase program. During October 2015, the Board of Directors increased the authorization under the share repurchase program detailed in Note 10 from \$30,000,000 to \$50,000,000.

The timing and amount of future repurchases, if any, will depend upon the Company's stock price, economic and market conditions, regulatory requirements, and other corporate considerations. The Company may initiate, suspend or discontinue purchases under the stock repurchase program at any time.

#### Contingencies

See Part II, Item 1. Legal Proceedings herein.

#### Contractual Obligations

Contractual obligations associated with ongoing business activities are expected to result in cash payments in future periods. The table below summarizes the amounts and estimated timing of these future cash payments as of September 30, 2015 (in thousands):

		Less than			
Contractual Obligations	TOTAL	1 year	1-3 years	3-5 years	Thereafter
Capital lease obligations	\$163	\$122	\$41	\$	\$—
Operating lease obligations	6,537	1,764	3,636	1,137	_
Charitable contribution obligations	200	200			
Meeting space commitments	1,092	609	483		
	\$7,992	\$2,695	\$4,160	\$1,137	<b>\$</b> —

#### Discussion of cash flows

Net cash from operations during the nine months ended September 30, 2015, increased approximately \$5.9 million to approximately \$14.5 million compared to \$8.5 million from operating activities for the nine months ended September 30, 2014, primarily attributable to an increase in net income compared to the prior year, partially offset by an increase in net working capital, and an increase in adjustments to net income for share-based compensation.

Net cash used in investing activities during the nine months ended September 30, 2015, was approximately \$2.3 million compared to approximately \$2.3 million for 2014. Funds were used to purchase equipment to expand production capacity and capitalize patent application costs.

Net cash used in financing activities during the nine months ended September 30, 2015, increased approximately \$14.7 million to \$17.7 million of cash used compared to \$3.0 million of cash used during the nine months ended September 30, 2014. Cash flows used in financing activities during the nine months include approximately \$21.1 million for stock repurchases, partially offset by approximately \$3.5 million from the exercise of stock options. For the nine months ended September 30, 2014, the Company received approximately \$2.4 million in total from the exercise of warrants and stock options and used approximately \$5.3 million for stock repurchases. Due to the material amount of non-cash related items included in the Company results of operations, the Company reports an Adjusted EBITDA metric which provides management with a clearer view of operational use of cash (see the table below). The Company's Adjusted EBITDA for the three months ended September 30, 2015, was approximately \$11.8 million which is an improvement of \$4.5 million as compared to the three months ended September 30, 2014. The improvement was primarily the result of the generation of greater revenue and resulting net income compared to lower net income for the prior year. The Company's Adjusted EBITDA for the nine months ended September 30, 2015, was approximately \$31.1 million which is an improvement of approximately \$19.0 million as compared to the nine months ended September 30, 2014. The improvement was primarily the result of the generation of greater revenue and resulting net income compared to lower net income for the prior year. Adjusted EBITDA is a non-GAAP measure. Non-GAAP financial measures are commonly used in the industry and are presented because management believes they provide relevant and useful information to investors. However, there are limitations to using these non-GAAP financial measures. Adjusted EBITDA is not indicative of cash provided or used by operating activities and may differ from comparable information provided by other companies. Adjusted EBITDA should not be considered in isolation, as an alternative to, or more meaningful than measures of financial performance determined in accordance with GAAP. The following table presents a reconciliation of Adjusted EBITDA to Net income, the most comparable financial measure reported under GAAP, for the three and nine months

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net Income (Per GAAP)	\$6,551	\$3,700	\$16,068	\$2,387
Add back:				
Income Taxes	158	22	527	22
Other Interest (Income) Expense, net	5	9	18	39
Depreciation Expense	470	313	1,247	864
Amortization Expense	234	232	699	695
Share-Based Compensation	4,378	3,022	12,564	8,161
Income Before Interest, Taxes, Depreciation,				
Amortization and Share-Based Compensation (Adjusted EBITDA)	\$11,796	\$7,298	\$31,123	\$12,168

ended September 30, 2015 and 2014 (in thousands), respectively.

#### **Critical Accounting Policies**

In preparing financial statements, the Company follows accounting principles generally accepted in the United States, which require the Company to make certain estimates and apply judgments that affect its financial position and results of operations. Management continually reviews the Company's accounting policies and financial information disclosures. A summary of significant accounting policies that require the use of estimates and judgments in preparing the financial statements was provided in the Company's Annual Report on Form 10-K for the year ended December 31, 2014. During the quarter covered by this report, there were no material changes to the accounting policies and assumptions previously disclosed.

**Recent Accounting Pronouncements** 

For the effect of recent accounting pronouncements, see Note 2 to the Condensed Consolidated Financial Statements contained herein.

Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk Not applicable.

#### Item 4. Controls and Procedures

Disclosure Controls and Procedures

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the Company carried out an evaluation of the effectiveness of the design and operation of its disclosure controls and procedures as of the end of the period covered by this report. This evaluation was carried out under the supervision and with the participation of Company management, including its Chief Executive Officer and Chief Financial Officer. Based upon that evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's controls and procedures were effective as of the end of the period covered by this report. Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in the Company's reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed in the Company's reports filed under the Exchange Act is accumulated and communicated to management, including the Company's Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding disclosures.

Changes in Internal Control over Financial Reporting

There was no change in the Company's internal control over financial reporting that occurred during the quarter ended September 30, 2015, that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

Limitations on the Effectiveness of Controls

The Company has confidence in its internal controls and procedures. Nevertheless, management, including the Company's Chief Executive Officer and Chief Financial Officer, does not expect that the Company's disclosure procedures and controls or its internal controls will prevent all errors or intentional fraud. An internal control system, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of such internal controls are met. Further, the design of an internal control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all internal control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected.

#### PART II - OTHER INFORMATION

Item 1. Legal Proceedings

Following the publication of the Untitled Letter from the FDA regarding the Company's micronized products in September 2013, the trading price of the Company's stock dropped sharply and several purported class action lawsuits were filed against the Company and certain of its executive officers asserting violations of the Securities Act of 1933 and the Securities Exchange Act of 1934 with respect to various statements and alleged omissions related to the Company's belief that its products were 361 HCT/Ps, including its micronized products. These cases have now all been removed to, and consolidated in, the United States District Court for the Northern District of Georgia. By order dated December 9, 2013, the Court approved the appointment of a lead plaintiff and a lead counsel. A Consolidated Amended Class Action Complaint, containing substantially the same causes of action and claims for relief as the initial complaints, was filed on January 27, 2014. The plaintiffs filed a motion to certify the proposed class on March 16, 2015, which defendants opposed on May 15, 2015, while also moving to exclude plaintiffs' expert. No ruling on either motion has been issued and the case is currently in the discovery phase. The Company currently believes that the outcome of this litigation will not have a material adverse impact on the Company's financial position or results of operations.

In the fourth quarter of 2014, the Company received a subpoena from the Office of Inspector General, U.S. Department of Health and Human Services, or OIG, in connection with a civil investigation into matters primarily related to the Company's sales and marketing activities. In March 2015, the Company received notice from the

Department of Justice that it declined at that time to intervene in the qui tam action that gave rise to the issuance of the subpoena. The qui tam plaintiff had 120 days from the date of the Department of Justice's notice to proceed with the case. The 120 day period passed without initiation of the lawsuit. The plaintiff, who is an executive at the Company's competitor Organogenesis, Inc., voluntarily dismissed the lawsuit in July 2015. This dismissal was approved by the Court on October 6, 2015.

On April 22, 2014, the Company filed a patent infringement lawsuit against Liventa Bioscience, Inc. ("Liventa"), Medline Industries, Inc. ("Medline") and Musculoskeletal Transplant Foundation, Inc. ("MTF") for permanent injunctive relief and unspecified damages. In addition to the allegations of infringement of MiMedx's patents, the lawsuit asserts that Liventa and

Medline knowingly and willfully made false and misleading representations about their respective products to providers, patients, and in some cases, prospective investors (the "Liventa Action"). The Liventa Action was filed in the United States District Court for the Northern District of Georgia.

MiMedx asserts that Liventa (formerly known as AFCell Medical, Inc.), Medline and MTF infringed and continue to infringe certain of the Company's patents relating to the MiMedx dehydrated human amnion/chorion membrane ("dHACM") allografts. MTF is the tissue processor while Liventa and Medline are the distributors of the allegedly infringing products. On May 30, 2014, defendants filed answers to the Complaint, denying the allegations in the Complaint. They also raised affirmative defenses of non-infringement, invalidity, laches and estoppel. MTF and Medline also filed counterclaims seeking declaratory judgments of non-infringement and invalidity. With the parties close to ending document discovery, fact depositions are currently being scheduled. Meanwhile, claim construction briefing is complete and the parties await the Court's guidance on a date for the Markman hearing. In patent litigation, a Markman hearing is also called a claim construction hearing, in which a judge decides what the language of a patent means as a matter of law.

On May 16, 2014, the Company also filed a patent infringement lawsuit against Transplant Technology, Inc. d/b/a Bone Bank Allografts ("Bone Bank") and Texas Human Biologics, Ltd. ("Biologics") for permanent injunctive relief and unspecified damages (the "Bone Bank Action"). The Bone Bank Action was filed in the United States District Court for the Western District of Texas. This lawsuit similarly asserts that Bone Bank and Biologics infringed certain of the Company's patents through the manufacturing and sale of their placental-derived tissue graft products. On July 10, 2014, defendants filed an answer to the Complaint, denying the allegations in the Complaint. They also raised affirmative defenses of non-infringement and invalidity and filed counterclaims seeking declaratory judgments of non-infringement and invalidity. The Bone Bank Action is in an advanced stage. The parties have (i) substantially completed document production; (ii) taken several fact depositions (both party and non-party); and (iii) completed claim construction briefing. The Markman hearing in this case was held on October 2, 2015.

In addition to defending the claims in the pending district court litigations, defendants in each case have challenged certain of the Company's patents in several inter-partes review proceedings to avoid the high burden of proof of proving invalidity by "clear and convincing evidence" in the district court litigations. An inter partes review (or "IPR") is a request for a specialized group within the United States Patent and Trademark Office to review the validity of a plaintiff's patent claims. The defendants in the Bone Bank Action have challenged the validity of the Company's 8,597,687 and 8,709,494 patents (the "'687" and "'494" patents, respectively); while the defendants in the Liventa Action have challenged the validity of the Company's 8,372,437 and 8,323,701 patents (the "437" and "701" patents, respectively). On June 29, 2015, the Patent Trial and Appeals Board ("PTAB") denied defendants' request for institution of an IPR with respect to the '494 patent on all seven challenged grounds. On August 18, 2005, the PTAB also denied defendants' request for institution of an IPR with respect to the '701 patent on all six challenged grounds. That is, the PTAB decided in each case that the defendants failed to establish a reasonable likelihood that defendants would prevail in showing any of the challenged claims of the '494 or the '701 patent were unpatentable. On July 10, 2015 the PTAB issued an opinion allowing a review of the '687 patent to proceed, although on only two of the five challenged grounds. The PTAB also adopted MiMedx's construction of the claims which will govern the Board's review of the '687 patent. On August 18, 2015, the PTAB issued an opinion allowing a review of the '437 patent to proceed, although only on one of the seven challenged grounds.

Following the PTAB decisions, the defendants in the Bone Bank Action moved to stay the district court litigation, despite the Court's previous denial of such a stay, pending the outcome of the '687 patent inter partes review. The parties agreed to stay the case with respect to the '687 patent only and the Court denied Bone Bank's motion to stay the litigation with respect to the '494 patent. The Company has also successfully defeated an attempt by defendants in the Liventa Action to stay that litigation -- also pending the outcome of the inter-partes review of the patents at issue in that case.

Finally, on March 2, 2015, the Company filed a patent infringement lawsuit against NuTech Medical, Inc. ("NuTech") and DCI Donor Services, Inc. ("DCI") for permanent injunctive relief and unspecified damages. This lawsuit was filed in the United States District Court for the Northern District of Alabama. The lawsuit alleges that NuTech and DCI have infringed and continue to infringe the Company's patents through the manufacture, use, sale, and/or offering of their tissue graft product. The lawsuit also asserts that NuTech knowingly and willfully made false and misleading representations about its products to customers and/or prospective customers. On April 17, 2015, NuTech filed a motion to dismiss the case purportedly for lack of patentable subject matter, which the Company has opposed. NuTech also filed a motion to stay the case pending disposition of the motion to dismiss, which MiMedx also opposed, and on which the Court declined to rule. Hearing on the motion to dismiss occurred on August 20, 2015; no ruling on the motion to dismiss has yet been issued.

#### Item 1A. Risk Factors

There have been no material changes to the risk factors previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2014.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On May 12, 2014, MiMedx Group, Inc. (the "Company") announced that its Board of Directors had authorized the repurchase of up to \$10,000,000 of its common stock from time to time through December 31, 2014. In subsequent amendments to the repurchase program, the Board extended the program until December 31, 2015 and the repurchase authorization was increased to \$30,000,000. During the month of October 2015, the Board further increased the repurchase authorization to \$50,000,000. The timing and amount of future repurchases, if any, will depend upon the Company's stock price, economic and market conditions, regulatory requirements, and other corporate considerations. The Company may initiate, suspend or discontinue purchases under the stock repurchase program at any time. The following is a summary of the Company's stock repurchases, before brokerage commissions of approximately \$14,000, for the quarter ended September 30, 2015:

Total amount remaining July 1, 2015	Total number of shares purchased	Average price paid per share	Total amount spent under the plan	Remaining amount to be spent under the plan \$7,827,694
July 1, 2015 - July 31, 2015	_	<b>\$</b> —	<b>\$</b> —	\$7,827,694
August 1, 2015 - August 31, 2015	208,000	\$9.19	\$1,910,546	\$5,917,148
September 1, 2015 - September 30, 2015	247,200	\$10.12	\$2,502,298	\$3,414,850
Total for the quarter	455,200		\$4,412,844	

Item 3. Defaults Upon Senior Securities Not applicable.
Item 4. Mine Safety Disclosures Not applicable.
Item 5. Other Information None.

e Description
Articles of Incorporation as filed with the Secretary of State of Florida on March 31, 2008 (incorporated by reference to Exhibit 3.1 filed with the Registrant's Form 10-Q on August 8, 2013)
Articles of Amendment to Articles of Incorporation as filed with the Secretary of the State of Florida on May 14, 2010 (incorporated by reference to Exhibit 3.2 filed with the Registrant's Form 10-Q on August 8, 2013)
Articles of Amendment to Articles of Incorporation as filed with the Secretary of the State of Florida on August 8, 2012 (incorporated by reference to Exhibit 3.3 filed with the Registrant's Form 10-Q on August 8, 2013)
Articles of Amendment to Articles of Incorporation as filed with the Secretary of the State of Florida on November 8, 2012 (incorporated by reference to Exhibit 3.4 filed with the Registrant's Form 10-Q on August 8, 2013)
Articles of Amendment to Articles of Incorporation as filed with the Secretary of the State of Florida on May 15, 2015 (incorporated by reference to Exhibit 3.5 filed with the Registrant's Form 10-Q on August 7, 2015)
Bylaws of MiMedx Group, Inc. (incorporated by reference to Exhibit 3.2 filed with Registrant's Form 8-K filed on April 2, 2008)
Amendment to the Bylaws of MiMedx Group, Inc. adopted by the Board of Directors on May 11, 2010 (incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K filed on May 14, 2010)
Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
XBRL Instance Document XBRL Taxonomy Extension Schema Document XBRL Taxonomy Extension Calculation Linkbase Document XBRL Taxonomy Extension Definition Linkbase Document XBRL Taxonomy Extension Label Linkbase Document XBRL Taxonomy Extension Presentation Linkbase Document

# Filed herewith

#### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized. November 6, 2015

By: /s/ Michael J. Senken Michael J. Senken Chief Financial Officer

(principal financial and accounting

officer)