MiMedx Announces Filing of 2018 Annual Report

March 17, 2020

Annual Report on Form 10-K includes Audited Financial Results for 2016 (restated), 2017 and 2018
2018 Net Sales of $359.1 million
Reflects Revenue Recognition on Cash Basis for all Years

MARIETTA, Ga., March 17, 2020 /PRNewswire/ -- MiMedx Group, Inc. (OTC PINK: MDXG) ("MiMedx" or "the Company"), an industry leader in advanced wound care and an emerging therapeutic biologics company, today announced the filing of its 2018 Annual Report, which includes the Company's audited consolidated statements of operations, and stockholders' equity and cash flows for the years ended December 31, 2018 and 2017, which the Company did not previously file, and for the year ended December 31, 2016, which the Company has restated.

Timothy R. Wright, MiMedx Chief Executive Officer, said: "The filing of our 2018 10-K is a significant milestone that repositions MiMedx for the future and reflects our commitment to serving urgent patient and physician needs. By instilling a culture of operational excellence, supportive of future growth and profitability, and making investments into the optimization of our Manufacturing, Research & Development, and Commercial organizations, we are positioning the Company to continue delivering evidence-based, advanced technologies that elevate the standard of care."

MiMedx continues to focus on supporting the steadily growing advanced wound care market, including investment in both clinical programs and health economics research to demonstrate the cost effectiveness of our products. Commercial efforts are aimed at category awareness, illustrating the impact of untreated wounds, and refining our sales messaging platforms. Operationally, the Company is transforming its business by strategically enhancing each functional area; implementing measures for sustainable compliance and improvement; and optimizing manufacturing processing efficiencies that support the transition of clinical and regulatory parameters for regenerative medicine. Efforts are also underway to complete and file the annual report on Form 10-K for the year ended December 31, 2019. The Company plans to announce the date of its annual meeting of shareholders shortly after it files its annual report on Form 10-K for the year ended December 31, 2019.

Highlight of Key Metrics

- 2018 net sales of $359.1 million.
- Restated net sales are $480.1 million from 2014-2016, representing a difference of $70.4 million compared to originally reported cumulative net sales of $550.5 million.
- A significant portion of the restatement difference is due to revenue recognition when payment was received. Refer to "Recent Developments" below for more information.
- Net loss of $30.0 million for 2018 reflects $51.3 million of investigation, restatement and related expenses.
- 2018 Adjusted EBITDA of $69.1 million[1].

	Years Ended December 31, (in thousands)	
	2018	**2017**
Net sales	$ 359,111	$ 321,139
Net (loss) income	(29,979)	64,727
EBITDA	3,519	50,853
Adjusted EBITDA	69,082	73,976
Net (loss) income per common share – basic	$ (0.28)	$ 0.61
Net (loss) income per common share – diluted	$ (0.28)	$ 0.56

1. Adjusted EBITDA is a non-GAAP financial measure. See "Reconciliation of GAAP Net Income to Adjusted EBITDA" for a reconciliation of Adjusted EBITDA to Net (loss) income, located in "Selected Financial Information" of this release.

	Years Ended December 31, (in thousands)		
	2016	2015	2014
Restated Revenue	$ 221,712	$ 153,131	$ 105,257
Adjustments	23,303	34,165	12,966
Originally Reported	$ 245,015	$ 187,296	$ 118,223

Net sales were $359.1 million in 2018, of which micronized products contributed $68.4 million. Growth in net sales from 2017 to 2018 was 11.8%, resulting primarily from favorable insurance coverage developments (that resulted in an increase in the number of units sold) and increases in the number of sales personnel, both through the third quarter of 2018. Further, revenues recorded on a cash basis benefited from sales made in prior periods and collected during the current period. These effects were partially offset by unfavorable insurance coverage developments, negative publicity resulting from actions taken in response to the Audit Committee investigation and governmental enforcement matters involving the Company and its former officers, and increased turnover of experienced sales personnel later in the year.

Gross margin in 2018 was 89.9%, compared to 89.0% in 2017. Gross margin increased in part due to the mix of products sold, as well as an improvement in yield, resulting from improved manufacturing efficiency in the wound care line.

Research and development expenses decreased 11.9% from 2017 to 2018, due primarily to year-over-year decreases in clinical trial activities, completion of studies initiated in prior periods, and a reduction in pre-clinical study investment.

Selling, General and Administrative ("SG&A") expense for 2018 increased 17.4% compared to 2017. Sales and Marketing expense included in SG&A increased 8.7% for 2018, primarily due to an increase in compensation related to the additional headcount and sales commissions. In 2018, general and administrative expense included in SG&A increased by $25.0 million, including fees for legal and consulting services, additional headcount (prior to the December 2018 reduction in force), as well as an increase in accounting fees due to the change in audit firms in mid-2018. Investigation, restatement, and related expenses were $51.3 million in 2018.

Food and Drug Administration (FDA) Audit

In December 2019, the Food and Drug Administration (FDA) conducted inspections at both of our processing facilities. These inspections measured the Company's compliance with the current good manufacturing practice (cGMP) standards required for tissue-based products that are regulated as drugs or biological products. The FDA issued a Form 483 for both facilities at the conclusion of each inspection. MiMedx provided timely responses to the FDA regarding each 483 observation, including responses to all of the observations and commitments to corrective actions. The Company has completed approximately half of the committed remedial actions to date, and expects to complete the remaining actions during the course of 2020, prior to the expiration of the FDA's enforcement discretion period with respect to the investigative new drug application and pre-market approval requirements applicable to certain Human Cells, Tissues and Cellular and Tissue Based Products, such as our micronized, injectable products.

Mr. Wright commented, "MiMedx is committed to sustained compliance at all levels of the organization, and we are confident in the safety and quality of our products. As a leader of this important therapeutic category, we welcome FDA guidance to elevate regulatory standards and will continue to partner proactively with the Agency. We have activated updates based on recent FDA feedback, and will continue to implement improvements to further strengthen the Company's quality systems in line with the recent FDA guidance. I am confident that a transparent and open dialogue with the FDA, along with a solution-oriented approach, will further support our commitment to safety and compliance."

The Company's most recent FDA inspection for compliance with current good tissue practice (cGTP) regulations, which took place in September 2018, resulted in no observations and a no action indicated (NAI) rating, which is the most favorable designation the FDA provides after such an inspection. The transition of manufacturing from cGTP to cGMP standards generally involves implementation of additional process controls, procedural documentation, and finished goods lot testing, among other things. The Company has advanced numerous proactive initiatives including leadership changes, third-party engagement, and overall systems improvements to support the enhanced regulation of the regenerative medicine category, along with transparent reporting of developments to the Agency.

M. Kathleen Behrens, Ph.D., Chair of the MiMedx Board of Directors, said, "A robust quality culture starts at the top, and the revitalized leadership team is committed to providing sustained, visible support for quality initiatives and consistently communicating the Company's quality standards and expectations to all personnel. The patients we serve are the focus of all our efforts. MiMedx is taking comprehensive action with an unwavering dedication to advancing the clinical and regulatory standards by which our products are evaluated before they reach patients. "

Recent Developments

As previously disclosed, the Company entered into a Term Loan Agreement in June 2019, borrowing $75 million, to facilitate implementation of its strategic priorities and accelerate the Company's timeline to achieve its long-term growth objectives, including the Biologics License Application (BLA) pipeline. The proceeds of the Term Loan Facility have additionally been used for working capital, general corporate purposes, and certain contingent liabilities of the Company. The Company is currently in compliance with the financial covenants in the Term Loan Agreement.

We expect that during 2019, the uncertainties of contractual adjustments with our customers will no longer be present such that we would be in a position to determine that an accounting contract exists at the time of physical delivery of our product to the customer. As of the date we filed our 2018 Form 10-K, the effective date of such transition was not certain. In light of this uncertainty and in the interests of providing additional information to investors regarding our results of operations for 2019, the estimates provided below regarding our 2019 performance were prepared for the entire year ended December 31, 2019 assuming that the Company continued to recognize revenue when payment was received after being adjusted for the amount expected to be refunded or credited to customers for sales returns made after payment. We expect that, once we determine the timing of the transition to a basis upon which revenue will be recognized at the time of physical delivery of the product to the customer, the final audited financial information will differ from that presented below to reflect additional revenue in 2019 in connection with such transition. We expect the amounts shipped and billed but not recorded as revenue at that date to be recognized as revenue over the following 60-90 days, consistent with our normal collection periods. At December 31, 2018, $51.0 million had been shipped and billed but not recorded as revenue.

- We expect 2019 revenue to decline from 2018 revenue between 25% to 28%, due to the continuation of trends that began in late 2018, including unfavorable insurance coverage developments, negative publicity resulting from the investigations, increased turnover of experienced sales personnel, and related events, as well as the discontinuation of certain products in 2019.
- We expect our 2019 gross profit percentage to be down 5% to 6% as compared to 2018 due to higher manufacturing costs and the impact of lower volumes.
- We expect research and development expenses for 2019 to decline as compared to 2018 due to the completion of certain research initiatives and a reduction in headcount.

- For 2019, we expect investigation, restatement, and related expenses to increase as compared to 2018 by $15 to $25 million due to costs incurred in connection with the completion of the investigations, the restatement, and the resolution of various related matters.
- We expect other expense to increase in 2019 as compared to 2018 by approximately $5 million due to interest expense related to our $75 million Term Loan Agreement, which was funded on June 10, 2019 (and which was not outstanding in 2018).

Our expectations for 2019 results are based on our results in the year; however, these results are unaudited and subject to period-end adjustments, along with uncertainty regarding when, and if, we will return to accrual accounting for revenue recognition. We caution the reader that actual results may differ materially from those described above.

In the second half of 2019 and the beginning of 2020, we believe our revenues stabilized. However, given the uncertainty regarding the impact on the economy from the COVID-19 virus, we are unable to provide any commentary regarding 2020 financial metrics. See Item 1A, "Risk Factors," within the Company's 2018 Annual Report.

Important Cautionary Statement

We caution the reader that actual results may differ materially from our expectations. Among the factors that could cause actual results to differ are: variances from our expectations or assumptions; changes in reimbursement policy from public and private insurers and health systems; the loss of a group purchasing organization ("GPO") or integrated delivery network ("IDN"); changes in purchasing behavior by government accounts; the loss of independent sales agents or distributors; the removal of any of our products from the market as a result of regulatory actions; the success of our marketing efforts; the fact that obtaining and maintaining the necessary regulatory approvals for certain of our products will be expensive and time consuming and may impede our ability to fully exploit our technologies; rapid technological change could cause our products to become obsolete and, if we do not enhance our product offerings through our research and development efforts, we may be unable to compete effectively; our ability to transition our manufacturing facilities into compliance with cGMP, advance our investigative new drug ("IND") applications, complete our clinical trials and pursue biologics license applications ("BLAs") for certain of our micronized products; the fact that our business is subject to continuing regulatory compliance by the FDA and other authorities, which is costly, and our failure to comply could result in negative effects on our business, results of operations and financial condition; the fact that litigation and other matters relating to and arising out of the Investigation, including the accounting review of our previously issued consolidated financial statements and the audits of fiscal years 2018, 2017 and 2016, have been time consuming and expensive, and may result in additional expense; and the fact that our variable rate indebtedness under the Term Loan Agreement subjects us to interest rate risk, which could result in higher expense in the event of increases in interest rates and adversely affect our business, financial condition, and results of operations. In addition, we discuss other factors in Item 1A, "Risk Factors," within the Company's 2018 Annual Report on Form 10-K.

About MiMedx

MiMedx® is an industry leader in advanced wound care and an emerging therapeutic biologics company developing and distributing human placental tissue allografts with patent-protected processes for multiple sectors of healthcare. The Company processes the human placental tissue utilizing its proprietary PURION® process methodology, among other processes, to produce allografts by employing aseptic processing techniques in addition to terminal sterilization. MiMedx has supplied over 1.8 million allografts, through both direct and consignment shipments. For additional information, please visit www.mimedx.com.

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Selected Financial Information

MiMedx Group, Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 45,118	$ 27,476
Inventory, net	15,986	9,467
Prepaid expenses	6,673	2,125
Income tax receivable	454	656
Other current assets	5,818	9,023
Total current assets	74,049	48,747
Other assets	48,795	72,508
Total assets	$ 122,844	$ 121,255
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 14,864	$ 8,454
Accrued compensation	23,024	20,941

Accrued expenses	31,842	15,768
Other current liabilities	1,817	647
Total current liabilities	71,547	45,810
Other liabilities	1,642	1,648
Total liabilities	73,189	47,458
Total stockholders' equity	49,655	73,797
Total liabilities and stockholders' equity	$ 122,844	$ 121,255

MiMedx Group, Inc.
Consolidated Statements of Operations
(in thousands, except percentage data)

	Years Ended December 31,		Change	
	2018	2017	$	%
Net sales	$ 359,111	$ 321,139	$ 37,972	11.8 %
Cost of sales	36,386	35,219	1,167	3.3 %
Gross profit	322,725	285,920	36,805	12.9 %
Operating expenses:				
Selling, general and administrative	258,528	220,119	38,409	17.4 %
Investigation, restatement and related	51,322	—	51,322	100.0 %
Research and development	15,765	17,900	(2,135)	(11.9) %
Amortization of intangible assets	1,034	1,678	(644)	(38.4) %
Operating (loss) income	(3,924)	46,223	(50,147)	(108.5) %
Other income (expense)				
Loss on divestiture of Stability	—	(1,048)	1,048	(100.0) %
Other income (expense), net	527	(87)	614	(705.7) %
(Loss) income before income tax provision	(3,397)	45,088	(48,485)	(107.5) %
Income tax provision (expense) benefit	(26,582)	19,639	(46,221)	(235.4) %
Net (loss) income	$ (29,979)	$ 64,727	$ (94,706)	(146.3) %

MiMedx Group, Inc.
Condensed Consolidated Statement of Cash Flows
(in thousands)

	Years Ended December 31,		
	2018	2017	2016
			(Restated)
Cash flows from operating activities:			
Net (loss) income	$ (29,979)	$ 64,727	$ 390
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation	5,882	4,087	3,333
Amortization of intangible assets	1,034	1,678	2,137
Amortization of inventory fair value step-up	—	203	1,485
Amortization of deferred financing costs	137	176	151
Amortization of discount on notes receivable	(190)	(12)	—
Change in fair value of earn-out consideration	—	(3,560)	(1,650)
Intangible asset impairment	—	590	—
Share-based compensation	14,768	21,195	17,732
Change in deferred income taxes	25,541	(26,670)	(5,992)
Loss on divestiture of Stability	—	1,048	—
Increase (decrease) in cash, net of effects of acquisition and divestiture, resulting from changes in the balance sheet	18,603	(523)	6,263
Net cash flows provided by operating activities	35,796	62,939	23,849
Cash flows from investing activities:			
Purchases of property and equipment	(9,419)	(5,126)	(6,205)
Proceeds from property and equipment sale	30	—	—
Principal payments from note receivable	778	—	—
Stability acquisition	—	—	(7,631)

Fixed maturity securities redemption	—	—	3,000
Patent application costs	(609)	(271)	(842)
Net cash flows used in investing activities	(9,220)	(5,397)	(11,678)
Cash flows from financing activities:			
Proceeds from exercise of stock options	3,555	11,987	3,494
Shares repurchased under repurchase plan	(7,572)	(68,263)	(10,378)
Shares repurchased for tax withholdings on vesting of restricted stock	(4,914)	(4,082)	(1,165)
Payments under capital lease obligations	(3)	(29)	(102)
Net cash flows used in financing activities	(8,934)	(60,387)	(8,151)
Net change in cash	17,642	(2,845)	4,020
Cash and cash equivalents, beginning of year	27,476	30,321	26,301
Cash and cash equivalents, end of year	$ 45,118	$ 27,476	$ 30,321

Reconciliation of GAAP Net Income to Adjusted EBITDA

Adjusted EBITDA is a non-GAAP financial measure representing (loss)/earnings before interest, taxes, depreciation and amortization, purchased intangible amortization, loss on divestiture, one-time inventory costs, investigation and restatement costs, share-based compensation and impairment of intangibles. This non-GAAP financial measure has certain limitations, including lacking standardized meaning, which may be different from similar non-GAAP financial measures used by other companies and/or analysts. Thus, it may be more difficult to compare our financial performance to that of other companies. We believe our reporting adjusted EBITDA assists investors in evaluating our operating performance. Because adjusted EBITDA is not a measure of financial performance calculated in accordance with GAAP, it should be considered in addition to, not a substitute for, other measures of our financial performance reported in accordance with GAAP, such as net (loss)/income.

	Years Ended December 31,		Change	
	(in thousands, except percentage data)			
	2018	2017	$	%
Net (loss) income	$ (29,979)	$ 64,727	$ (94,706)	(146) %
Non-GAAP Adjustments:				
Depreciation expense	5,882	4,087	1,795	44 %
Amortization of intangible assets	1,034	1,678	(644)	(38) %
Income tax provision	26,582	(19,639)	46,221	(235) %
EBITDA	$ 3,519	$ 50,853	$ (47,334)	(93) %
Additional Non-GAAP Adjustments:				
Loss on divestiture	—	1,048	(1,048)	(100) %
One-time inventory fair value adjustments in connection with acquisition	—	203	(203)	(100) %
Costs incurred in connection with investigation and restatement	51,322	—	51,322	100 %
Interest (income) expense, net	(527)	87	(614)	(706) %
Impairment of intangible assets	—	590	(590)	(100) %
Share-based compensation	14,768	21,195	(6,427)	(30) %
Adjusted EBITDA	$ 69,082	$ 73,976	(4,894)	(7) %

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