

# Interpace Diagnostics Group Reports Fourth Quarter and Full Year 2017 Financial Results, Business Progress Against Plan and Recent Accomplishments

Revenue for the Quarter Grew 40% over the Comparable Prior Year Quarterand 21% for the Full Year, Raising \$30 Million in Equity and Significantly Improving Balance Sheet and Cash Position, Reimbursement Continued to Grow Especially for ThyGenX® and ThyraMIR®

Conference Call Thursday March 15, 2018 at 4:30 p.m. ET

PARSIPPANY, N.J., March 15, 2018 (GLOBE NEWSWIRE) -- Interpace Diagnostics Group, Inc. (Nasdaq:IDXG) ("Interpace" or the "Company"), a fully integrated commercial and bioinformatics company that provides clinically useful molecular diagnostic tests and pathology services, today announced financial results and business progress for the quarter and full year ended December 31, 2017 as well as recent accomplishments.

"2017 definitively positioned IDXG as a force in the growing molecular diagnostics and bioinformatics sector as we delivered strong, sequential revenue growth, improved margins, and greatly improved liquidity during a period characterized by enhanced reimbursement and volume growth in our endocrine or (thyroid) franchise as well as growth in our gastrointestinal or (pancreas) franchise," said Jack Stover, Interpace's President and CEO. "During the year we raised approximately \$30 million in capital and eliminated over \$9 million of secured debt and royalties to further strengthen our balance sheet, providing the capital needed to keep us on a sustainable path during 2017 and 2018," said Stover.

## Q4 and 2017 Year End Financial Results and Performance

- Revenue for the three and twelve-month periods ended December 31, 2017 was \$4.4 million and \$15.9 million, respectively, an increase of 40% and 21% over the prior year periods principally as a result of our endocrine (thyroid) franchise but also due to growth in our gastroenterology (pancreas) franchise as well. Revenue for the three-month period ended December 31, 2017 also grew 4.0% over the preceding quarter.
- Gross profit percentage improved from 49.2% to 53.7% year over year, while improving for the fourth quarter from 43.2% in 2016 to 62.5% in 2017, as we began to recognize the benefits of scale as well as reduce certain royalty obligations.
- General & Administrative costs decreased for the three and twelve-month periods ended December 31, 2017 over the prior year periods by 4% and 13%, respectively.
- Sales & Marketing costs increased for the three and twelve-month periods ended

December 31, 2017 over the prior year periods by 61% and 20%, respectively, supporting our revenue growth and reflecting the rational rebuilding of our commercial operations to take advantage of market opportunities.

- Research & Development costs decreased for the three and twelve-month periods ended December 31, 2017 over the prior year periods by 16% and 11%, respectively.
- Loss from Continuing Operations for the three and twelve-month periods ended December 31, 2017 was (\$5.0) million and (\$12.7) million, respectively, while Income (Loss) from Continuing Operations for the three and twelve-month periods of the prior year was \$6.3 million and (\$8.4) million, respectively.
- Net Income (Loss) for the three and twelve-month periods ended December 31, 2017 was (\$5.0) million and (\$12.2) million, respectively, and \$6.3 million and (\$8.3) million for the comparable periods of the prior year.
- Adjusted EBITDA (in the attached schedule), which we believe is a meaningful supplemental disclosure that may be indicative of how management and our Board of Directors evaluate Company performance, adjusts Income or Loss from Continuing Operations for non-cash charges such as depreciation & amortization, stock-based compensation, asset impairment, loss on extinguishment, the change in fair value of both our contingent consideration and certain warrant liabilities. Accordingly, our Adjusted EBITDA for the three-and twelve-month periods ended December 31, 2017 was (\$1.6) and (\$7.1) million, respectively, an improvement of 45% and 32%, respectively, over the (\$2.9) and (\$10.5) million for the comparable periods of the prior year.
- Our cash balance at the end of the year was \$15.2 million, up from \$0.6 million at the end of 2016 and our stockholders' equity balance is approximately \$40 million as of December 31, 2017, up from \$6.5 million at the end of 2016.

## 2017 and Recent Business Highlights

## Reimbursement:

- UnitedHealthcare, the largest health plan in the United States, agreed to cover our ThyraMIR® test, our microRNA-based molecular test used in assessing indeterminate thyroid nodules.
- We signed a new national contract with Aetna for our ThyGenX ® and ThyraMIR® tests covering many of Aetna's products. The agreement is our first national provider contract with a national health plan and means that Interpace will now be part of Aetna's laboratory network for these services.
- Cigna, one of the largest national health plans in the United States, agreed to cover Interpace's ThyGenX test for Cigna's 15 million members nationwide.
- Oxford Health Plans began to cover Interpace's ThyraMIR test. Oxford offers health care benefits to employers primarily in New York, New Jersey, and Connecticut making it one of the largest health plans in the heavily populated tristate Region.
- The American Medical Association (AMA) assigned a new, discreet CPT code to facilitate reimbursement of ThyraMIR simplifying and expediting the process for Interpace in submitting claims and securing reimbursement.

- Medicare reimbursement for ThyGenX increased by 40% effective January 1, 2018. Medicare represents approximately 40% of the Company's volume for the ThyGenX test.
- In 2018 we announced that five Blue Cross Blue Shield plans agreed to cover both ThyGenX and ThyraMIR. These five plans combined represent over 8 million members who now have coverage for the Company's molecular thyroid tests.

## Commercial Expansion:

- We announced the renewal and expansion of our agreement with Lab Corp, a NYSE listed company which provides leading-edge medical laboratory tests and services through a national network of primary clinical laboratories and specialty testing laboratories, to now co-market ThyraMIR along with ThyGenX.
- We announced that the New York State Department of Health has reviewed and approved our TERT marker of aggressiveness which can now be ordered in conjunction with the ThyGenX molecular panel or on a stand-alone basis.
- We also announced that the Company has entered into a Laboratory Services Agreement with ARUP Laboratories, Inc., whereby ARUP is utilizing Interpace as a laboratory services provider for its menu of molecular testing services.

## Clinical Evidence

- We commenced a multi-site study to provide further evidence of the Clinical Utility of our ThyGenX/ThyraMiR tests in accurately identifying malignancy or benign status in indeterminate thyroid nodules.
- We announced the data presented in six posters at the Digestive Disease Week (DDW) meeting including:

Three posters supporting the clinical utility of PancraGEN® in assessing longterm risk of malignancy in pancreatic cystic lesions and three posters supporting the clinical utility of PancraGEN as an ancillary test for solid lesions of the pancreas and bile duct.

- We also announced the presentation of new data based on actual clinical results for 3,471 patients tested with ThyGenX/ThyraMIR at the annual meeting of The American Thyroid Association (ATA).
- We reported two publications presented at the WCOG American College of Gastroenterology (ACG) 2017 Conference.
- We also announced that G2 Intelligence selected Interpace as the "Company of the Month for September 2017".
- In January 2018 we announced that CIO Applications magazine designated Interpace as one of the top 20 Companies in 2017 for providing bioinformatics solutions to their

customers through the Company's extensive data base, and,

• In February 2018 we announced the acceptance of five abstracts of the Company being presented at the US and Canadian Academy of Pathology (USCAP).

"Based on our accomplishments in 2017 and progress to date in scaling operations, gaining additional reimbursement and expanding our commercial activities, we are pleased with our performance in 2017 and we are looking forward to 2018," concluded Stover.

## About Thyroid Nodules, ThyGenX and ThyraMIR testing

According to the American Thyroid Association, approximately 15% to 30% of the 525,000 thyroid fine needle aspirations (FNAs) performed on an annual basis in the U.S. are indeterminate for malignancy based on standard cytological evaluation, and thus are candidates for ThyGenX and ThyraMIR.

ThyGenX and ThyraMIR reflex testing yields high predictive value in determining the presence and absence of cancer in thyroid nodules. The combination of both tests can improve risk stratification and surgical decision-making when standard cytopathology does not provide a clear diagnosis for the presence of cancer.

ThyGenX utilizes state-of-the-art next-generation sequencing (NGS) to identify more than 100 genetic alterations associated with papillary and follicular thyroid carcinomas, the two most common forms of thyroid cancer. ThyraMIR is the first microRNA gene expression classifier. MicroRNAs are small, non-coding RNAs that bind to messenger RNA and regulate expression of genes involved in human cancers, including every subtype of thyroid cancer. ThyraMIR measures the expression of 10 microRNAs. Both ThyGenX and ThyraMIR are covered by both Medicare and Commercial insurers.

## About PancraGEN

PancraGEN® is a molecular test that stratifies the risk of progression to pancreatic cancer from pancreatic cysts and solid masses by incorporating endoscopic ultrasound images, cytology, first-line chemistry testing like CEA and Amylase, and molecular markers into one of four risk categories ranging from Benign to Aggressive. PancraGEN® is 90% accurate according to clinical studies, enabling effective risk stratification of patients. Pancreatic cancer is often difficult to diagnose in early stages and typically spreads rapidly with signs and symptoms appearing when the cancer is significantly advanced. Because of this, and that complete surgical removal of the pancreas is not possible, pancreatic cancer is considered a leading cause of cancer deaths.

# About RespriDx

RespriDx<sup>™</sup> is a molecular test that differentiates between new primary lung tumors and metastasis by identifying the unique molecular fingerprint of a tumor using a series of tumor markers and loss of heterozygosity (LOH). Discerning whether a lung neoplasm is the result of a newly formed tumor or metastasis is useful in determining what course of action physicians should take, e.g. surgery, chemotherapy, etc.

## About Interpace Diagnostics Group, Inc.

Interpace is a fully integrated commercial and bioinformatics company that provides clinically useful molecular diagnostic tests and pathology services for evaluating risk of cancer by leveraging the latest technology in personalized medicine for improved patient diagnosis and management. The Company currently has four commercialized molecular tests and one test in a clinical evaluation process (CEP); PancraGEN® for the diagnosis and prognosis of pancreatic cancer from pancreatic cysts; ThyGenX® for the diagnosis of thyroid cancer from thyroid nodules utilizing a next generation sequencing assay; ThyraMIR® for the diagnosis of thyroid cancer from thyroid nodules utilizing a proprietary gene expression assay; and RespriDX<sup>™</sup> that differentiates lung cancer of primary vs. metastatic origin. BarreGEN® for Barrett's Esophagus, is currently being "soft launched" with key opinion leaders as we continue to gather data on this assay that will assist us in seeking favorable reimbursement as well as important clinical information. [Barrett's Esophagus is a rapidly growing diagnosis that affects over three million people in the US and over time can progress to esophageal cancer.] The Company's data base includes data from over 45,000 patients who have been tested using the Company's current products, including over 15,000 molecular tests for thyroid nodules. Interpace has been designated as one of the top 20 companies for providing bioinformatics solutions. Interpace's mission is to provide personalized medicine through molecular diagnostics, innovation and data to advance patient care based on rigorous science. For more information, please visit Interpace's website at www.interpacediagnostics.com

## **Forward Looking Statements**

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, relating to the Company's future financial and operating performance, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond the Company's control. These statements also involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results to be materially different from those expressed or implied by any forward-looking statement. Known and unknown risks, uncertainties and other factors include, but are not limited to, the Company's history of losses, the Company's ability to adequately finance the business, the market's acceptance of its molecular diagnostic tests, its ability to retain or secure reimbursement, its ability to secure additional business and generate higher profit margins through sales of its molecular diagnostic tests, in-licensing or other means, projections of future revenues, growth, gross profit and anticipated internal rate of return on investments and its ability to maintain its NASDAQ listing. Additionally, all forward-looking statements are subject to the "Risk Factors" detailed from time to time in the Company's SEC filings, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2017 to be filed, Quarterly Reports on Form 10-Q and other SEC filings.

Because of these and other risks, uncertainties and assumptions, undue reliance should not be placed on these forward-looking statements. In addition, these statements speak only as of the date of this press release and, except as may be required by law, the Company undertakes no obligation to revise or update publicly any forward-looking statements for any reason.

## CONTACTS:

Interpace Diagnostics Group, Inc.

#### INTERPACE DIAGNOSTICS GROUP, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED) (in thousands, except per share data)

	Three Months Ended December 31,			Years Decem		
		2017		2016	 2017	 2016
Revenue, net Cost of revenue	\$	4,370 1,639	\$	3,122 1,774	\$ 15,897 7,358	\$ 13,085 6,641
Gross Profit		2,731		1,348	 8,539	 6,444
Sales and marketing Research and development General and administrative		2,060 259 2,723		1,276 308 2,848	6,567 1,461 9,153	5,462 1,647 10,504
Acquisition related amortization expense		813		862	3,253	3,770
Asset impairment Change in fair value of contingent		-		-	-	3,363
consideration		174		(10,686)	 (5,602)	 (11,860)
Total operating expenses		6,029		(5,392)	 14,832	 12,886
Operating (loss) income		(3,298)		6,740	(6,293)	(6,442)
Interest expense		-		(544)	(433)	(2,144)
Loss on extinguishment of debt		-		-	(4,278)	-
Other (expense) income, net		(1,713)		-	 (2,128)	 14
Loss from continuing operations before tax		(5,011)		6,196	(13,132)	(8,572)
Income tax benefit		(55)		(108)	 (395)	 (162)
(Loss) income from continuing operations		(4,956)		6,304	(12,737)	(8,410)
Discontinued Operations Income (loss) from discontinued operations Gain on sale of assets		43		120 -	 1,124 -	 (886) 1,326
Income from discontinued operations		43		120	1,124	440
Provision for income tax on discontinued operations		94		143	 603	 362
Income from discontinued operations, net of tax	\$	(51)	\$	(23)	\$ 521	\$ 78
Net (loss) income	\$	(5,007)	\$	6,281	\$ (12,216)	\$ (8,332)
Basic (loss) income per share of common stock:						
From continuing operations	\$	(0.18)	\$	3.40	\$ (0.81)	\$ (4.63)

From discontinued operations Net (loss) income per basic share of common stock	(0.00)		(0.01)		0.03		0.04	
	\$	(0.19)	\$	3.39	\$	(0.77)	\$	(4.59)
Diluted (loss) income per share of common stock:								
From continuing operations	\$	(0.18)	\$	3.25	\$	(0.81)	\$	(4.63)
From discontinued operations		(0.00)	_	(0.01)		0.03		0.04
Net (loss) income per diluted share of common stock	\$	(0.19)	\$	3.24	\$	(0.77)	\$	(4.59)
Weighted average number of common shares and								
common share equivalents outstanding:								
Basic		26,874		1,855		15,766		1,816
Diluted		26,874		1,941		15,766		1,816

# Selected Balance Sheet Data (Unaudited) (\$ in thousands)

	December 31,		De	ecember 31,
	2017			2016
Cash and cash equivalents	\$	15,199	\$	602
Total current assets		19,808		4,240
Total current liabilities		7,991		16,241
Total assets		53,598		41,778
Total liabilities		13,629		35,247
Total stockholders equity		39,969		6,531

## Selected Cash Flow Data (Unaudited) (\$ in thousands)

	For the Years Ended December 31,					
		2017		2016		
Net loss	\$	(12,216)	\$	(8,332)		
Net cash used in operations	\$	(15,263)	\$	(7,607)		
Net cash used in investing activities		(29)		-		
Net cash provided by (used in) financing activities		29,889		(101)		
Change in cash and cash equivalents		14,597		(7,708)		
Cash and equivalents, Beginning		602		8,310		
Cash and equivalents, Ending	\$	15,199	\$	602		

## **Non-GAAP Financial Measures**

In addition to the United States generally accepted accounting principles, or GAAP, results provided throughout this document, Interpace has provided certain non-GAAP financial measures to help evaluate the results of its performance. We believe that these non-GAAP financial measures, when presented in conjunction with comparable GAAP financial measures, are useful to both management and investors in analyzing the Company's ongoing business and operating performance. We believe that providing the non-GAAP information to investors, in addition to the GAAP presentation, allows investors to view the Company's financial results in the way that management views financial results.

In this document, we discuss Adjusted EBITDA, a non-GAAP financial measure. Adjusted EBITDA is a metric used by management to measure cash flow of the ongoing business. Adjusted EBITDA is defined as income or loss from continuing operations, plus depreciation and amortization, non cash stock based compensation, interest and taxes, and other non-cash expenses including asset impairment costs, loss on extinguishment of debt, goodwill impairment and change in fair value of both our contingent consideration and certain warrant liabilities. The table below includes a reconciliation of this non-GAAP financial measure to the most directly comparable GAAP financial measure.

		rs Ended nber 31,		Years Ended December 31,			
	2017	2016	2017	2016			
(Loss) income from continuing operations Depreciation and amortization- continuing	\$ (4,956 )	\$ 6,304	\$ (12,737)	\$ (8,410)			
operations	876	992	3,690	4,292			
Stock-based compensation - continuing							
operations	583	23	1,060	131			
Taxes	(55)	(108)	(395)	(162)			
Interest expense	-	544	433	2,144			
Mark to market on warrant liability	(260)	-	141	-			
Warrant expense	2,016	-	2,016	-			
Asset impairment	-	-	-	3,363			
Loss on extinguishment of debt	-	-	4,278	-			
Change in fair value of contingent consideration	174	(10,686)	(5,602)	(11,860)			
Adjusted EBITDA	\$ (1,622 )	\$ (2,931)	\$ (7,116)	\$ (10,502)			

#### Reconciliation of Adjusted EBITDA (Unaudited) (\$ in thousands)

# **Conference Call**

As previously announced, Interpace will hold a conference call today Thursday, March 15, 2018 at 4:30 PM (ET) to discuss financial and operational results for the fourth quarter and the year ended December 31, 2017. Details as follows:

Time: 4:30 PM (ET) Dial-in numbers: toll free: 1-888-394-8218 (US) toll/international 1-323-701-0225 Conference ID#: 5146319 The live webcast and subsequent replay may be accessed by visiting Interpace's website: <u>www.interpacediagnostics.com</u>. The webcast replay will be available on the company's website within 24 hours following completion of the call and archived on the company's website for 90 days.



Source: Interpace Diagnostics Group, Inc.