

November 13, 2018



# Interpace Diagnostics Reports Third Quarter 2018 Financial Results, Business Progress and Recent Accomplishments

*Conference Call Tuesday, November 13, 2018 at 4:30 pm ET*

PARSIPPANY, NJ,, Nov. 13, 2018 (GLOBE NEWSWIRE) -- Interpace Diagnostics Group, Inc. (NASDAQ: IDYG), a fully integrated commercial and bioinformatics company that provides clinically useful molecular diagnostic tests and pathology services for improved patient diagnosis and management, today announced financial results and business progress for the quarter ended September 30, 2018, as well as recent accomplishments.

Topline highlights include:

- *Expanded Guidance of Revenues for the Year to a Range between \$21 and \$22 Million*
- *Revenue Grew to \$5.8 Million in the Third Quarter 2018 or 37% over the Third Quarter 2017*
- *Year to Date Revenue of \$16.1 Million Increased 39% over the Same Period of 2017*
- *Cash & Cash Equivalents of \$8.0 Million; No Long-Term Debt*
- *Added \$4.0 Million Line of Credit Availability*
- *Now Covered by 30 Regional Blue Cross/Blue Shield Plans for ThyGenX<sup>®</sup> and ThyraMIR<sup>®</sup>*

Jack Stover, President and CEO of Interpace Diagnostics, said, "I am very pleased to report the third quarter of 2018 continues our track record of revenue growth with seven straight quarters of gains in both volume and reimbursement." Mr. Stover continued, "Our thyroid and pancreatic franchises more than met our expectations. The expansion of our thyroid franchise with the launch of our new and expanded mutational panel, ThyGeNEXT<sup>™</sup>, the addition of thyroid coverage by new 30 Blue Cross/Blue Shield plans including the BCBS Federal Employee Health Benefit Program with 5.3 million covered lives, as well as concurrent growth in evaluating thyroid slide biopsies, supported by the recent transition of former Rosetta Genomics customers, has provided us with the experience and confidence to expand our guidance for 2018 Revenues to range between \$21 and \$22 million."

## **Q3 2018 Financial Performance**

- Revenue for the three-month period ended September 30, 2018, was \$5.8 million, an increase of 37% over the second quarter 2017. Revenue year-to-date was \$16.1 million, an increase of 39% over the comparable period in 2017. Quarter over quarter revenue growth for the third quarter was 5% over the second quarter.
- Gross Profit percentage for the quarter was 52%, up from 51% for the third quarter of

2017 and gross profit year-to-date was 53% as compared to 50% for the prior comparable year-to-date period.

- Operating Loss was \$(2.5) million for the quarter ended September 30, 2018, compared to an Operating Loss of \$(3.1) million for the third quarter of 2017. Year-to-date Operating Loss was \$(7.6) million as compared to an Operating Loss of \$(3.0) million for the same period of 2017. The 2017 Operating Loss included \$5.8 million of non-cash reduction of expenses related to a change in fair value of contingent consideration.
- Net Cash Used in Operating Activities year-to-date was approximately \$6.8 million as compared to \$12.9 million year to date in 2017. A significant portion of the 2017 net cash used was related to discontinued operations and transaction costs.
- Net Loss for the third quarter of 2018 was \$(3.0) million, as compared to \$(3.3) million for the third quarter of 2017, a 10% improvement. Our year-to-date Net Loss of \$(8.2) million compared to a \$(7.2) million Net Loss for the comparable year-to-date period ended September 30, 2017, which included, as previously stated, an offset to expenses of \$5.8 million related to a non-cash change in fair value of contingent consideration in 2017.
- Basic and Diluted Net Loss per Common Share for the third quarter of 2018 was \$(0.11) versus \$(0.15) for the prior year quarter, and \$(0.29) versus \$(0.60) for the year-to-date comparable quarters.
- 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, interest and taxes, mark to market on warrant liabilities, loss on extinguishment of debt, and the change in fair value of contingent consideration, for the three-month periods ended September 30, 2018 and 2017 was \$(1.0) million and \$(1.9) million, respectively. Year-to-date Adjusted EBITDA for the nine-month period ended September 30, 2018 was \$(3.4) million as compared to \$(5.5) million for the comparable period of 2017. The improvement in Adjusted EBITDA was principally due to our increased Revenues in 2018.
- Cash and Cash Equivalents were \$8.0 million at September 30, 2018; there was no long-term debt and Stockholders' Equity amounted to \$36.0 million at September 30, 2018. Additionally, an up to \$4 million line of credit is now available to assist in funding our working capital needs as well as anticipated lab expansions.

### **Third Quarter 2018 and Recent Business Highlights**

Our most important progress for the quarter and year-to-date includes the following:

- Expanding our PancreGEN<sup>®</sup> assay beyond just pancreatic cysts to include both biliary strictures and solid pancreatic lesions,
- Adding year to date 30 Blue Cross/Blue Shield plans to cover our thyroid assays as well as CIGNA now covering ThyraMIR<sup>®</sup> (in addition to its previously approved policy to cover ThyGeNEXT<sup>™</sup>).
- Most recently announcing new insurance BC/BS coverage by the Federal Employee Health Benefit Program of 5.3 million covered lives to utilize our thyroid assays,
- Announcing at the American Thyroid Association (ATA) release of interim results of our registry data study supporting the use of ThyGeNEXT<sup>™</sup> and ThyraMIR<sup>®</sup>,

- Receiving approval from Piedmont General Hospital, Georgia's largest healthcare system, to cover PancraGEN<sup>®</sup>,
- Completing the transition of the Rosetta business to our commercial team utilizing slides to assess the potential progression of indeterminate thyroid biopsies. Also acquiring most of the equipment of Rosetta's Philadelphia lab to assist us in the expansion of our own clinical labs, and
- As mentioned in the previous quarter, successfully launching ThyGeNEXT<sup>™</sup> our proprietary new expanded mutational panel for indeterminate thyroid nodules, at the (AACE) Annual Meeting.

## **Pipeline Progress**

Our pipeline progress is principally focused in the following areas:

1. Expansion of new product extensions from existing products, following a similar strategy like we did for ThyGeNEXT<sup>™</sup>.
2. Acquiring or developing new products similar to what we did by seeking approval to evaluate slide biopsies for our thyroid assays and expanding this opportunity as we did with the assumption of much of the former Rosetta Genomics business, and,
3. Developing new products on an existing platform like we are doing with BarreGEN<sup>®</sup> for Barrett's Esophagus.

We are also focused on offering and potentially partnering our data and capabilities in bioinformatics and continuing to expand our product offerings by utilizing and leveraging our commercial team, who have access to many high-level physicians in Gastrointestinal and Endocrine practices and, therefore, in acquiring or licensing in products while also seeking expansion of our product offerings outside of the U.S.

## **BarreGEN<sup>®</sup> Franchise**

- BarreGEN<sup>®</sup> is our major pipeline product focus. Our CEP or Clinical Evaluation Program continues to build as we gather additional data and results of sophisticated users.
- We are working on our second clinical validity study to support the ability of BarreGEN<sup>®</sup> to identify patients at risk of progression to esophageal cancer years prior to any visible signs of cancer.
- We are also in discussions with the Centers for Medicare & Medicaid Services about coverage of BarreGEN<sup>®</sup>.
- Additionally, we are now performing clinical assessment evaluations of BarreGEN<sup>®</sup> in use with devices commonly used in Barrett's Esophagus procedures. We will be keeping you advised of our assessment and progress.

We continue to believe that we have the opportunity to be a leader in this important disease state and provide critical information to potentially improve the standard of care in managing the progression of Barrett's Esophagus.

## **Conference Call**

Interpace will hold a conference call on Tuesday, November 13, 2018 at 4:30 p.m. to discuss financial and operational results for the third quarter and year-to-date ended September 30, 2018 and answer questions. Details are as follow:

**Date and Time:** Tuesday, November 13, 2018 at 4:30 p.m. ET

**Dial-in Number (Domestic):** (877) 407 - 0312

**Dial-in Number (International):** +1 (201) 389 - 0899

**U.K. Dial-in Number:** +1 (800) 756 - 3429

**Confirmation Number:** 136 849 48

**Webcast Access:** <https://webcasts.eqs.com/interpace20181113>

The webcast replay will be available on the company's website approximately two hours following completion of the call and archived on the company's website for 90 days.

### **About Interpace Diagnostics Group, Inc.**

Interpace is a fully integrated commercial and bioinformatics company that provides clinically useful molecular diagnostic tests bioinformatics 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<sup>®</sup> for the diagnosis and prognosis of pancreatic cancer from pancreatic cysts; ThyGenX<sup>®</sup> (now ThyGeNEXT<sup>™</sup>) for the diagnosis of thyroid cancer from thyroid nodules utilizing a next generation sequencing assay; ThyraMIR<sup>®</sup> 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. In addition, BarreGEN<sup>®</sup> 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 25,000 molecular tests for thyroid nodules. Interpace has been designated by the 2017 edition of *CIO Applications* 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](http://www.interpacediagnostics.com).

### **About ThyGeNEXT<sup>™</sup> and ThyraMIR<sup>®</sup>**

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 ThyGeNEXT<sup>™</sup> and ThyraMIR<sup>®</sup>.

ThyGeNEXT<sup>™</sup> and ThyraMIR<sup>®</sup> 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.

ThyGeNEXT™ utilizes state-of-the-art next-generation sequencing (NGS) to identify more than 100 genetic alterations associated with papillary and follicular and medullary 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, and through a proprietary algorithm, provides insight of cancer risk. Both ThyGeNEXT™ and ThyraMIR® are covered by both Medicare and Commercial insurers.

ThyGeNEXT™ is a proprietary newly expanded mutational panel for indeterminate thyroid nodules. ThyGeNEXT™ includes numerous additional molecular markers, gene mutations, and RNA fusions compared to ThyGenX®. The new product represents a more comprehensive set of indicators to not only identify malignant or benign nodules, but also ascertain aggressiveness and other characteristics.

### **About PancraGEN®**

PancaGEN® is a molecular test for pancreatic cysts and pancreaticobiliary solid lesions that, by using a small sample of pancreatic cyst fluid or biopsy, can aid in pancreatic cancer risk assessment. PancraGEN® is 90% accurate in pancreatic cysts 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, pancreatic cancer is a leading cause of cancer deaths.

### **About RespriDxÔ**

RespriDx™ 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 of critical importance when determining appropriate and effective patient management, e.g. surgery, chemotherapy, neoadjuvant treatment, etc.

### **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. The Company has attempted to identify forward looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "potential," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are based on current expectations, assumptions and uncertainties involving judgments about, among other things, future economic, 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 ability to adequately finance the business, its ability to restructure its liabilities and other obligations, 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 most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q.*

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#### **Non-GAAP Financial Measures**

In addition to the United States generally accepted accounting principles, or GAAP, results provided throughout this press release, 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, mark to market on warrant liability, and other non-cash expenses including loss on extinguishment of debt, and change in fair value of contingent consideration. The table below includes a reconciliation of this non-GAAP financial measure to the most directly comparable GAAP financial measure.

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Revenue, net	\$ 5,753	\$ 4,202	\$ 16,062	\$ 11,527
Cost of revenue	2,763	2,069	7,590	5,719
Gross Profit	2,990	2,133	8,472	5,808
Sales and marketing	2,048	1,816	6,135	4,507
Research and development	510	483	1,528	1,202
General and administrative	2,084	2,116	5,981	6,431
Amortization expense	813	813	2,439	2,439
Change in fair value of contingent consideration	-	-	-	(5,776 )
Total operating expenses	5,455	5,228	16,083	8,803
Operating loss	(2,465 )	(3,095 )	(7,611 )	(2,995 )
Interest expense	(248 )	(40 )	(248 )	(433 )
Loss on extinguishment of debt	- #	-	-	(4,278 )
Other expense, net	(288 )	(294 )	(143 )	(414 )
Loss from continuing operations before tax	(3,001 )	(3,429 )	(8,002 )	(8,120 )
Provision (benefit) for income taxes	7	(42 )	21	(340 )
Loss from continuing operations	(3,008 )	(3,387 )	(8,023 )	(7,780 )
(Loss) income from discontinued operations, net of tax	\$ (34 )	\$ 71	\$ (129 )	\$ 572
Net loss	\$ (3,042 )	\$ (3,316 )	\$ (8,152 )	\$ (7,208 )
Basic (loss) income per share of common stock:				
From continuing operations	\$ (0.11 )	\$ (0.15 )	\$ (0.29 )	\$ (0.65 )
From discontinued operations	(0.00 )	0.00	(0.00 )	0.05
Net loss per basic share of common stock	\$ (0.11 )	\$ (0.15 )	\$ (0.29 )	\$ (0.60 )
Diluted (loss) income per share of common stock:				
From continuing operations	\$ (0.11 )	\$ (0.15 )	\$ (0.29 )	\$ (0.65 )
From discontinued operations	(0.00 )	0.00	(0.00 )	0.05

Net loss per diluted share of common stock	<u>\$ (0.11 )</u>	<u>\$ (0.15 )</u>	<u>\$ (0.29 )</u>	<u>\$ (0.60 )</u>
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Weighted average number of common shares and common share equivalents outstanding:

Basic	28,215	22,028	28,002	12,022
Diluted	28,215	22,028	28,002	12,022

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

	<u>September 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
Cash and cash equivalents	\$ 8,002	\$ 15,199
Total current assets	18,245	19,808
Total current liabilities	7,762	8,091
Total assets	49,801	53,598
Total liabilities	13,772	13,729
Total stockholders equity	36,029	39,869

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

	<b>For the Nine Months Ended</b> <b>September 30,</b>	
	<u>2018</u>	<u>2017</u>
Net loss	\$ (8,152 )	\$ (7,208 )
Net cash used in operations	\$ (6,800 )	\$ (12,884 )
Net cash used in investing activities	(388 )	(29 )
Net cash (used in) provided by financing activities	(9 )	24,014
Change in cash and cash equivalents	(7,197 )	11,101
Cash and equivalents, Beginning	15,199	602
Cash and equivalents, Ending	<u>\$ 8,002</u>	<u>\$ 11,703</u>

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

<u>Quarters Ended</u> <u>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>



Loss from continuing operations	\$ (3,008 )	\$ (3,387 )	\$ (8,023 )	\$ (7,780 )
Depreciation and amortization	870	876	2,580	2,813
Stock-based compensation	525	271	1,564	477
Taxes	7 #	(42 )	21 #	(340 )
Interest expense	248	40	248	433
Mark to market on warrant liability	325	325	259	401
Loss on extinguishment of debt	-	-	-	4,278
Change in fair value of contingent consideration	-	-	-	(5,776 )
Adjusted EBITDA	<u>\$ (1,033 )</u>	<u>\$ (1,917 )</u>	<u>\$ (3,351 )</u>	<u>\$ (5,494 )</u>



Source: Interpace Diagnostics Group, Inc.