

August 9, 2018



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

*Revenue Grew 43% Over the Prior Year's Quarter and 14% Over the Prior Period*

*Record Quarterly Revenue of \$5.5 Million*

*Cash & Cash Equivalents of \$10.1 Million with No Long-Term Debt*

*Now Covered by 27 Regional Blue Cross/Blue Shield Plan for ThyGenX® and ThyraMIR®*

*Company Successfully Launched New Mutational Panel for Thyroid: ThyGeNEXT™*

*Guidance of Revenues for the Year of Over \$20 Million Reaffirmed*

*Conference Call Thursday August 9, 2018 at 4:30 pm ET*

Parsippany, NJ, Aug. 09, 2018 (GLOBE NEWSWIRE) -- Interpace Diagnostics Group, Inc. (NASDAQ: IDXG) ("Interpace" or "the Company"), a fully integrated bioinformatics and commercial company that provides clinically useful molecular diagnostic tests, related first line assessments and pathology services for improved patient diagnosis and management, today announced financial results and business progress for the quarter ended June 30, 2018, as well as recent accomplishments.

Jack Stover, President and CEO of Interpace Diagnostics, said, "I am especially proud to follow an outstanding first quarter with an even stronger second quarter of 2018. We continued our quarter over quarter revenue growth, with both strong volume growth and gains in reimbursement especially in our Thyroid franchise, and I am very pleased to report our recent success in growing our important PancreaGEN® franchise as well; both contributing to record revenues." Mr. Stover continued, "The expansion of our thyroid franchise with the launch of our new and expanded mutational panel, ThyGeNEXT™, as well as the addition of 13 new Regional Blue Cross and Blue Shield Plans in the second quarter, (bringing to 27 new BC/BS plans added year to date), now covering ThyGeNEXT™ and ThyraMIR® helped support our exceptional growth. Accordingly, I am especially pleased to reaffirm our Revenue guidance for the year of over \$20 million," confirmed Stover.

**Q2 2018 Financial Performance**

- Revenue for the three-month period ended June 30, 2018 was \$5.5 million, an increase of 43% over the second quarter 2017, and 14% over the first quarter of 2018. Revenue year to date was \$10.3 million, an increase of 41% over the \$7.3 million in revenue for the same period in 2017.
  - Gross Profit percentage for the quarter was 59%, an increase from 51% from the same period of the prior year. Gross Profit percentage year to date was 53% compared to 50% for the comparable prior year period.
  - Operating Loss was \$(1.9) million for the quarter ended June 30, 2018, compared to an Operating Loss of \$(3.6) million for the second quarter of 2017. Cumulative year to date Operating Loss was \$(5.1) million through the second quarter of 2018, compared to Operating Income of \$0.1 million for the comparable period of 2017, which was principally due to the change in fair value of contingent consideration in 2017.
  - Net Cash Used in Operations for the quarter amounted to \$2.5 million, compared to \$4.4 million for the second quarter of 2017. Net Cash Used in Operations year to date was \$5.0 million as compared to \$8.6 million in the same period in 2017.
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- Included in Net Cash Used in Operations year to date was approximately \$1.0 million related to discontinued operations and transaction costs, compared to \$6.25 million for the six-month period ended June 30, 2017.
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- Net Loss for the quarter was \$(1.9) million, an improvement of 70% over the \$(6.3) million Net Loss in the same period in 2017 which included a \$2.7 million loss on extinguishment of debt. Our year to date Net Loss of \$(5.1) million compared to a \$(3.9) million Net Loss for the comparable period ended June 30, 2017, which included a \$5.8 million change in fair value of contingent consideration during the same six-month period in 2017.
  - Basic and Diluted Net Loss per Common Share for the quarter was \$(0.07) versus \$(0.65) for the prior year quarter, an improvement of 89%, and \$(0.18) and \$(0.57), or an improvement of 68% year to date as compared to the same period of last 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, 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 June 30, 2018 and 2017 was \$(0.6) million and \$(2.4) million, respectively, an improvement due principally to our increased Revenues in 2018. Year to date Adjusted EBITDA was \$(2.3) million as compared to \$(3.5) million for the comparable period of 2017.
  - Cash and Cash Equivalents were \$10.1 million; there was no long-term debt and Stockholders' Equity amounted to \$38.6 million at June 30, 2018.

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

### *Commercial Progress:*

- Successfully launched ThyGeNEXT™, our proprietary new mutational panel for indeterminate thyroid nodules, at the American Association of Clinical Endocrinologists (AACE) Annual Meeting.

- We entered into an Agreement with Vanderbilt University Medical Center (VUMC), one of the largest academic medical centers in the country, enabling all physicians across the Vanderbilt system access to both ThyGenX<sup>®</sup> (now ThyGeNEXT<sup>™</sup>) and ThyraMIR<sup>®</sup>.
- We entered into an Agreement with BJC Healthcare in St. Louis, providing access to both ThyGeNEXT<sup>™</sup> and ThyraMIR<sup>®</sup>.
- We launched the expansion of PancraGEN<sup>®</sup> beyond pancreatic cysts to include both biliary strictures and solid pancreatic lesions.
- Additionally, a number of former Rosetta Genomics thyroid customers began transitioning their business to us upon Rosetta's bankruptcy filing.

#### *Reimbursement Expansion:*

- Year to date, we announced 27 new Blue Cross Blue Shield plans across the country who have published favorable coverage policies for ThyGenX<sup>®</sup> (now ThyGeNEXT<sup>™</sup>) and ThyraMIR<sup>®</sup>.
- Also recently, CIGNA, one of the nation's largest health plan providers, agreed to cover ThyraMIR<sup>®</sup>, in addition to ThyGeNEXT<sup>™</sup>.

#### *Clinical Evidence:*

- Announced the acceptance of five abstracts by the American Thyroid Association for their upcoming October Annual Meeting.
- We are further progressing with our clinical validation study for ThyGeNEXT<sup>™</sup> and expect to submit for publication by the end of the third quarter.
- We successfully enrolled 9 institutions in a registry study for our thyroid tests to determine the impact of test results on patient outcomes and management decisions and plan to publish on interim results later this year or early next year.
- Presented new data on the incremental value of PancraGEN<sup>®</sup> to patient outcomes when used as a companion molecular diagnostic to traditional imaging modalities at the Digestive Disease Week (DDW) meeting.
- We announced the expansion of the application of PancraGEN<sup>®</sup> beyond pancreatic cysts to include both biliary strictures and solid pancreatic lesions, while gaining further guideline support with three studies supportive of the validity and utility of PancraGEN<sup>®</sup>.
- We further expanded the BarreGEN<sup>®</sup> Clinical Experience Program ("CEP") and made other progress, which we discuss later.

#### *Operational Progress:*

- In March we renewed our major laboratory lease in Pittsburgh and have since initiated a construction project to more than double the size of our CLIA and CAP certified lab.
- We also initiated the process of redesigning our website including our investor relations section to make it more user-friendly.
- On July 30<sup>th</sup> NASDAQ notified us that we were again in compliance with their minimum \$1.00 bid price requirement and the matter was determined to be closed.
- We expanded our in house billing and reimbursement team by two people focused on improving collections.

- We also successfully completed an independent assessment of our in-house Laboratory Information Systems (LIMS) and determined that it supported our ability to be able to scale up our business in the future and meet growing customer demands.

### *Pipeline Progress:*

Our Pipeline progress is principally focused in three critical areas. First and foremost is BarreGEN<sup>®</sup>; second is offering and partnering our data and capabilities in bioinformatics, and lastly acquiring or licensing in products while also seeking expansion of our product offerings outside of the US.

BarreGEN<sup>®</sup> is a major pipeline focus of ours in 2018 and likely, in 2019 as well.

- We are seeking and gaining KOL support of BarreGEN<sup>®</sup>.
- Importantly, 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 continuing to expand usage of BarreGEN<sup>®</sup> by way of our CEP program the purpose of which is to gather additional experience and data to seek physician adoption, guideline support and reimbursement and we plan to publish clinical utility data in the future.
- Furthermore, we are working to validate BarreGEN<sup>®</sup> on variable esophageal specimen types such that we can provide physicians with BarreGEN<sup>®</sup> options convenient to their individual practice.

Lastly, we continue to assess the use of BarreGEN<sup>®</sup> with other companion technologies where we believe that we have the opportunity to be a leader in this important disease state and provide critical risk assessments and information to potentially improve the standard of care.

### **Conference Call**

As previously announced, Interpace will hold a conference call Thursday, August 9, 2018 at 4:30 p.m. (ET) to discuss financial and operational results for the second quarter and year to date ended June 30, 2018. Details as follows:

Date and Time: August 9, 2018, 4:30 p.m. ET

US Telephone: 1-877-407-0312

International Telephone: 1-201-389-0899

Confirmation Number: 13682292

Webcast: <https://webcasts.eqs.com/interpace20180809>

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, related first line assays 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); PancreGEN® for the diagnosis and prognosis of pancreatic cancer from pancreatic cysts, biliary strictures and solid masses; ThyGenX® (now ThyGeNEXT™), for the diagnosis of thyroid cancer from thyroid nodules utilizing a next generation sequencing assay for indeterminate thyroid nodules that includes numerous additional molecular markers, gene mutations, and RNA fusions; ThyraMIR®, for the diagnosis of thyroid cancer from thyroid nodules utilizing a proprietary gene expression assay; and RespriDX™ 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 condition that affects over three million people in the US and over time can progress to esophageal cancer. The Interpace 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 by *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 Thyroid Nodules, ThyGenX® (now ThyGeNEXT™) 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 now ThyGeNEXT™) and ThyraMIR®.

ThyGenX® (and now ThyGeNEXT™) 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® (and now 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 ThyGenX® (and now 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 RespriDx™**

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, 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 net 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 December 31, 2017 Annual Report on Form 10-K filed with the SEC on March 23, 2018 and the Company's Form 10-Q's.*

*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:**

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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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenue, net	\$ 5,501	\$ 3,855	\$ 10,310	\$ 7,325
Cost of revenue	2,247	1,879	4,827	3,651
Gross Profit	3,254	1,976	5,483	3,674
Sales and marketing	2,095	1,555	4,086	2,691
Research and development	518	413	1,019	719
General and administrative	1,726	2,793	3,897	4,315
Acquisition related amortization expense	813	813	1,626	1,626
Change in fair value of contingent consideration	-	-	-	(5,776 )
Total operating expenses	5,152	5,574	10,628	3,575
Operating (loss) income	(1,898 )	(3,598 )	(5,145 )	99
Interest expense	-	(216 )	-	(469 )
Loss on extinguishment of debt	-	(2,731 )	-	(4,278 )

Other income (loss), net	33	(8 )	144	(44 )
Loss from continuing operations before tax	<u>(1,865 )</u>	<u>(6,553 )</u>	<u>(5,001 )</u>	<u>(4,692 )</u>
Provision (benefit) for income taxes	8	(301 )	14	(298 )
Loss from continuing operations	<u>(1,873 )</u>	<u>(6,252 )</u>	<u>(5,015 )</u>	<u>(4,394 )</u>
 (Loss) income from discontinued operations, net of tax	 <u>\$ (44 )</u>	 <u>\$ (54 )</u>	 <u>\$ (95 )</u>	 <u>\$ 502</u>
 Net loss	 <u>\$ (1,917 )</u>	 <u>\$ (6,306 )</u>	 <u>\$ (5,110 )</u>	 <u>\$ (3,892 )</u>
 Basic (loss) income per share of common stock:				
From continuing operations	\$ (0.07 )	\$ (0.65 )	\$ (0.18 )	\$ (0.64 )
From discontinued operations	<u>(0.00 )</u>	<u>(0.01 )</u>	<u>(0.00 )</u>	<u>0.07</u>
Net loss per basic share of common stock	<u>\$ (0.07 )</u>	<u>\$ (0.65 )</u>	<u>\$ (0.18 )</u>	<u>\$ (0.57 )</u>
 Diluted (loss) income per share of common stock:				
From continuing operations	\$ (0.07 )	\$ (0.65 )	\$ (0.18 )	\$ (0.64 )
From discontinued operations	<u>(0.00 )</u>	<u>(0.01 )</u>	<u>(0.00 )</u>	<u>0.07</u>
Net loss per diluted share of common stock	<u>\$ (0.07 )</u>	<u>\$ (0.65 )</u>	<u>\$ (0.18 )</u>	<u>\$ (0.57 )</u>
 Weighted average number of common shares and common share equivalents outstanding:				
Basic	27,933	9,657	27,894	6,877
Diluted	27,933	9,657	27,894	6,877

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

	<u>June 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
Cash and cash equivalents	\$ 10,084	\$ 15,199
Total current assets	19,205	19,808
Total current liabilities	7,354	8,091
Total assets	51,356	53,598
Total liabilities	12,804	13,729
Total stockholders equity	38,552	39,869

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

**For the Six Months Ended**

	<b>June 30,</b>	
	<u><b>2018</b></u>	<u><b>2017</b></u>
Net loss	\$ (5,110 )	\$ (3,892 )
Net cash used in operations	\$ (5,027 )	\$ (8,572 )
Net cash used in investing activities	(79 )	-
Net cash (used in) provided by financing activities	(9 )	22,235
Change in cash and cash equivalents	<u>(5,115 )</u>	<u>13,663</u>
Cash and equivalents, Beginning	15,199	602
Cash and equivalents, Ending	<u>\$ 10,084</u>	<u>\$ 14,265</u>

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

	<b>Quarters Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<u><b>2018</b></u>	<u><b>2017</b></u>	<u><b>2018</b></u>	<u><b>2017</b></u>
Loss from continuing operations	\$ (1,873 )	\$ (6,252 )	\$ (5,015 )	\$ (4,394 )
Depreciation and amortization	856	965	1,710	1,937
Stock-based compensation	442	148	1,040	206
Taxes	8	(301 )	14	(298 )
Interest expense	-	216	-	469
Mark to market on warrant liability	4	76	(66 )	76
Loss on extinguishment of debt	-	2,731	-	4,278
Change in fair value of contingent consideration	-	-	-	(5,776 )
Adjusted EBITDA	<u>\$ (563 )</u>	<u>\$ (2,417 )</u>	<u>\$ (2,317 )</u>	<u>\$ (3,502 )</u>



Source: Interpace Diagnostics Group, Inc.