
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(D) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): March 19, 2019

INTERPACE DIAGNOSTICS GROUP, INC.

(Exact name of Registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
of incorporation)

0-24249
(Commission
File Number)

22-2919486
(IRS Employer
Identification No.)

Morris Corporate Center 1, Building C
300 Interpace Parkway,
Parsippany, NJ 07054
(Address, including zip code, of Principal Executive Offices)

(855) 776-6419
Registrant's telephone number, including area code:

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition

On March 19, 2019, Interpace Diagnostics Group, Inc. issued a press release announcing its results of operations and financial condition for the fiscal year ended December 31, 2018. The full text of the press release is set forth as Exhibit 99.1 attached hereto and is incorporated herein by reference.

The information in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise stated in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit

Number Description

99.1 [Press Release dated March 19, 2019](#)

SIGNATURE

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 hereunto duly authorized.

Interpace Diagnostics Group, Inc.

/s/ Jack E. Stover

Jack E. Stover

President and Chief Executive Officer

Date: March 19, 2019

EXHIBIT INDEX

| Exhibit Number | Description |
|-------------------|--|
| 99.1 | Press Release dated March 19, 2019 |

Interpace Diagnostics Group Reports Full Year and Fourth Quarter 2018 Financial Results

Business Progress and Recent Accomplishments Highlighted and Discussed Further on Conference Call

PARSIPPANY, NJ, March 19, 2019 — Interpace Diagnostics Group, Inc. (NASDAQ: IDXG) (“Interpace” or the “Company”) today announced financial results for the full year and fourth quarter ended December 31, 2018, along with business progress and recent accomplishments.

Topline highlights include:

- *Net Revenue for 2018 was \$21.9 million, which increased 38% over 2017 Net Revenue;*
- *Net Revenue grew to \$5.8 million in the fourth quarter 2018, or 34% over the fourth quarter 2017;*
- *Cash & Cash Equivalents of \$6.1 million as of December 31, 2018; no Long-Term Debt outstanding;*
- *Raised \$6.1 million in net proceeds through an underwritten public offering in January 2019;*
- *Now covered by 30 regional Blue Cross Blue Shield (BCBS) plans for ThyGeNEXT® and ThyraMIR®; and*
- *Announced further progress developing lead pipeline product, BarreGEN® for Barrett’s Esophagus*

Jack Stover, President and CEO of Interpace Diagnostics, said, “This past year was a terrific year for Interpace as our thyroid (endocrine) franchise and our pancreatic (gastrointestinal) franchise both continued to grow as anticipated.” Mr. Stover continued, “With our recent completed public offering, the absorption of most of Rosetta Genomics’ business late in the year and our reduced cash spend, we are confident in our positioning and trajectory for 2019 and beyond.”

Full Year and Fourth Quarter 2018 Financial Results and Performance

- Net Revenue for the year ended 2018 was \$21.9 million, an increase of 38% over the comparable period in 2017. Net Revenue for the quarter was \$5.8 million, an increase of 34% over the fourth quarter of 2017.
 - Gross Profit percentage year-to-date was 53% as compared to 54% for the prior comparable year-to-date period and Gross Profit percentage for the quarter was 55%, down from 62% for the fourth quarter of 2017, principally due to the timing of purchases and product royalties.
 - The 2018 Operating Loss was \$(12.1) million as compared to an Operating Loss of \$(6.3) million for the same period of 2017. The 2017 Operating Loss included \$5.6 million of non-cash reduction of expenses related to a change in fair value of contingent consideration. Operating Loss was \$(4.5) million for the quarter ended December 31, 2018, compared to an Operating Loss of \$(3.3) million for the quarter ended December 31, 2017.
 - Net Cash Used in Operating Activities in 2018 was approximately \$(8.7) million as compared to \$(15.3) million in 2017, a 43% improvement. A significant portion of the 2017 net cash used was related to discontinued operations and transaction costs.
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- Our 2018 and 2017 Net Losses were both approximately \$(12.2) million, respectively. The 2017 Net Loss included, as previously stated, an offset to expenses of \$5.6 million related to a non-cash change in fair value of contingent consideration. Net Loss for the fourth quarter of 2018 was \$(4.0) million, as compared to \$(5.0) million for the fourth quarter of 2017, a 19% improvement.
- Basic and Diluted Net Loss per Common Share was \$(0.43) versus \$(0.77) for the comparable years and for the fourth quarter of 2018 was \$(0.14) versus \$(0.19) for the prior year quarter.
- 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. Adjusted EBITDA for the year ended December 31, 2018 was \$(4.7) million as compared to \$(7.1) million for the comparable period of 2017, a 34% improvement. The improvement in Adjusted EBITDA was principally due to our increased Revenues and continued cost controls in 2018. Adjusted EBITDA for the three-month periods ended December 31, 2018 and 2017 was \$(1.4) million and \$(1.6) million, respectively.
- Cash and Cash Equivalents were \$6.1 million at December 31, 2018; there was no long-term debt outstanding and Stockholders' Equity amounted to \$32.9 million at December 31, 2018. Additionally, in January 2019 we raised an additional \$6.1 million in net proceeds from a public offering generally with good quality biotech investors and in November 2018 closed on a \$4 million line of credit facility, which is now available to assist in funding our working capital needs as well as anticipated lab expansions.

Recent Business Highlights

Our most important business progress for 2018 and 2019 year-to-date includes the following:

- Announced further expansion of our thyroid business by offering tests under three distinct platforms;
- Entered into an agreement with University of Maryland medical system providing them access to our molecular tests;
- Added 30 new BCBS plans to cover our thyroid assays as well as CIGNA now covering ThyraMIR® (in addition to its previously approved policy to cover ThyGeNEXT®);
- Announced new insurance BCBS coverage by the Federal Employee Health Benefit Program of 5.3 million covered lives to utilize our thyroid assays;
- Announced at the American Thyroid Association (ATA) release of interim results of our registry data study supporting the use of ThyGeNEXT® and ThyraMIR®;
- Received approval from Piedmont General Hospital, Georgia's largest healthcare system, to cover PancreaGEN® and,
- Completed the conversion of Rosetta Genomics' business, which utilized slides to assess the potential progression of indeterminate thyroid biopsies, to our commercial team. Also acquired the majority of Rosetta's lab equipment as we expanded our own clinical labs.

Product and Pipeline Progress

Our product development and pipeline progress is principally focused in the following areas:

- We expanded our PancreaGEN® assay beyond just pancreatic cysts to include both biliary strictures and solid pancreatic lesions;
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- As mentioned in the previous quarter, we successfully launched ThyGeNEXT®, our proprietary new expanded mutational panel for indeterminate thyroid nodules, at the American Association of Clinical Endocrinologists (AACE) Annual Meeting;
- BarreGEN® is our major pipeline product focus. Our Clinical Evaluation Program (CEP) continues to build as we gather additional data and results of sophisticated users:
 - Dr. Tina Narick and Jim Camuti of Interpace have been selected to head the further development and clinical activities related to BarreGEN® in order to accelerate this process;
 - We launched our first Key Opinion Leader (KOL) group of prominent physicians to assist us in positioning BarreGEN® for the marketplace;
 - We announced that a Notice of Allowance was issued by the U.S. Patent and Trademark office supporting BarreGEN®;
 - We are working on our second clinical validity study to support the ability of BarreGEN® to identify patients at risk of progression to esophageal cancer years prior to any visible signs of cancer.
 - We are in discussions with the Centers for Medicare & Medicaid Services about coverage of BarreGEN®;
 - We are also continuing to discuss with potential partners the opportunity to co-develop as well as potentially co-market BarreGEN®; and
 - In 2019 we announced the first independent publication in *BMI Open Gastroenterology* demonstrating clinical utility of BarreGEN®.

We are also focused on the following business strategies:

- Offering and potentially partnering our data and capabilities in bioinformatics for opportunities to utilize our database of over 50,000 patient samples; and
- Continuing to expand our product offerings both in and outside of the U.S. either through acquisitions or licensing by leveraging our highly experienced commercial team.

Conference Call

Interpace will hold a conference call on Tuesday, March 19, 2019, at 4:30 p.m. ET to discuss financial and operational results for the year and fourth quarter ended December 31, 2018, and answer questions. Details are as follow:

Date and Time: Tuesday, March 19, 2019, at 4:30 p.m. ET
Dial-in Number (Domestic): (877) 407 – 0312
Dial-in Number (International): +1 (201) 389 – 0899
Confirmation Number: 136 88 229
Webcast Access: <https://webcasts.eqs.com/interpacedia20190319>

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

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); PancreGEN® for the diagnosis and prognosis of pancreatic cancer from pancreatic cysts; ThyGeNEXT® 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™ 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 50,000 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 2018 edition of *CIO Applications* as one of the top 10 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. 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 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 most recent Annual Report on Form 10-K, 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:

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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
(in thousands, except per share data)

| | Three Months Ended | | Years Ended | |
|--|--------------------|------------|--------------|-------------|
| | December 31, | | December 31, | |
| | (Unaudited) | | | |
| | 2018 | 2017 | 2018 | 2017 |
| Revenue, net | \$ 5,834 | \$ 4,370 | \$ 21,896 | \$ 15,897 |
| Cost of revenue | 2,607 | 1,639 | 10,197 | 7,358 |
| Gross Profit | 3,227 | 2,731 | 11,699 | 8,539 |
| Sales and marketing | 2,286 | 2,060 | 8,421 | 6,567 |
| Research and development | 596 | 259 | 2,124 | 1,461 |
| General and administrative | 2,518 | 2,723 | 8,499 | 9,153 |
| Amortization expense | 813 | 813 | 3,252 | 3,253 |
| Change in fair value of contingent consideration | 1,522 | 174 | 1,522 | (5,602) |
| Total operating expenses | 7,735 | 6,029 | 23,818 | 14,832 |
| Operating loss | (4,508) | (3,298) | (12,119) | (6,293) |
| Interest expense | (83) | - | (331) | (433) |
| Loss on extinguishment of debt | - | - | - | (4,278) |
| Other expense, net | 405 | (1,713) | 263 | (2,128) |
| Loss from continuing operations before tax | (4,186) | (5,011) | (12,187) | (13,132) |
| (Benefit) provision for income taxes | (3) | (55) | 18 | (395) |
| Loss from continuing operations | (4,183) | (4,956) | (12,205) | (12,737) |
| Income (loss) from discontinued operations, net of tax | \$ 146 | \$ (51) | \$ 16 | \$ 521 |
| Net loss | \$ (4,037) | \$ (5,007) | \$ (12,189) | \$ (12,216) |
| Basic (loss) income per share of common stock: | | | | |
| From continuing operations | \$ (0.15) | \$ (0.18) | \$ (0.43) | \$ (0.81) |
| From discontinued operations | 0.01 | (0.01) | 0.00 | 0.03 |
| Net loss per basic share of common stock | \$ (0.14) | \$ (0.19) | \$ (0.43) | \$ (0.77) |
| Diluted (loss) income per share of common stock: | | | | |
| From continuing operations | \$ (0.15) | \$ (0.18) | \$ (0.43) | \$ (0.81) |
| From discontinued operations | 0.01 | (0.01) | 0.00 | 0.03 |
| Net loss per diluted share of common stock | \$ (0.14) | \$ (0.19) | \$ (0.43) | \$ (0.77) |
| Weighted average number of common shares and common share equivalents outstanding: | | | | |
| Basic | 28,608 | 26,874 | 28,155 | 15,766 |
| Diluted | 28,608 | 26,874 | 28,155 | 15,766 |

Selected Balance Sheet Data
(\$ in thousands)

| | <u>December 31,</u> <u>2018</u> | <u>December 31,</u> <u>2017</u> |
|---------------------------|------------------------------------|------------------------------------|
| Cash and cash equivalents | \$ 6,068 | \$ 15,199 |
| Total current assets | 17,721 | 19,808 |
| Total current liabilities | 8,492 | 8,091 |
| Total assets | 48,442 | 53,598 |
| Total liabilities | 15,504 | 13,729 |
| Total stockholders equity | 32,938 | 39,869 |

Selected Cash Flow Data
(\$ in thousands)

| | For the Years Ended | |
|---|------------------------------------|------------------|
| | <u>December 31,</u> <u>2018</u> | <u>2017</u> |
| Net loss | \$ (12,189) | \$ (12,216) |
| Net cash used in operations | \$ (8,673) | \$ (15,263) |
| Net cash used in investing activities | (449) | (29) |
| Net cash (used in) provided by financing activities | (9) | 29,889 |
| Change in cash and cash equivalents | (9,131) | 14,597 |
| Cash and equivalents, Beginning | 15,199 | 602 |
| Cash and equivalents, Ending | <u>\$ 6,068</u> | <u>\$ 15,199</u> |

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

| | Quarters Ended | | Years Ended | |
|--|-----------------------|-------------------|---------------------|-------------------|
| | December 31, | | December 31, | |
| | <u>2018</u> | <u>2017</u> | <u>2018</u> | <u>2017</u> |
| Loss from continuing operations | \$ (4,183) | \$ (4,956) | \$ (12,205) | \$ (12,737) |
| Depreciation and amortization | 884 | 876 | 3,464 | 3,690 |
| Stock-based compensation | 706 | 583 | 2,270 | 1,060 |
| Taxes | (3) | (55) | 18 | (395) |
| Interest expense | 83 | - | 331 | 433 |
| Mark to market on warrant liability | (372) | (260) | (112) | 141 |
| Loss on extinguishment of debt | - | - | - | 4,278 |
| Warrant expense | - | 2,016 | - | 2,016 |
| Change in fair value of contingent consideration | 1,522 | 174 | 1,522 | (5,602) |
| Adjusted EBITDA | <u>\$ (1,363)</u> | <u>\$ (1,622)</u> | <u>\$ (4,712)</u> | <u>\$ (7,116)</u> |

