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DISCERNING DIAGNOSTIC UNCERTAINTY THROUGH MOLECULAR ANALYSIS

INTERPACE DIAGNOSTICS

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CIO APPLICATIONS TOP 10 BIOINFORMATICS SOLUTION PROVIDERS - 2018

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DISCERNING DIAGNOSTIC UNCERTAINTY THROUGH MOLECULAR ANALYSIS

By Shikha

Imagine a gastroenterologist sitting in his office pondering over reports of one of his patients with a suspicious pancreatic cyst. Whether to perform a surgery or carry out ongoing medical surveillance remains his dilemma. On the one hand, he is aware of the risks associated with surgeries while on the other, he is uncertain of the appropriate surveillance period before he observes any progression in the cyst. He looks for any missing piece of information during diagnosis and carries out several tests known as first-line tests such as cytology, chemistries such as CEA and Amylase, and imaging studies, e.g. MRI and CT scans. What if the results of all these modalities are indeterminate? In such an instance, he can perform molecular diagnostic tests to obtain valuable information and better predict whether a cyst will remain indolent or become malignant and reach a conclusion whether surveillance or surgery is the appropriate strategy.

Such insights can be obtained by performing molecular diagnostic tests using platforms offered by Interpace Diagnostics. New Jersey-based Interpace Diagnostics is a molecular diagnostic and bioinformatics company that enables physicians to make better and more informed treatment decisions about pancreatic cysts, thyroid nodules or other tumor types that can lead to cancer. The company offers several molecular products along with a database that contains information for patients that were tested using molecular diagnostics carried out by Interpace Diagnostics over the last several years. The molecular diagnostic test results of more than 45,000 patients with different types of cysts or tumors are stored in the database along with numerous other data elements that can be used for various applications, including population and disease management, companion diagnostics, and others. Also, the patients' data is updated in the database whenever a new result is obtained through ongoing molecular testing.

> "INTERPACE DIAGNOSTICS IS FOCUSED ON DEVELOPING AND COMMERCIALIZING MOLECULAR DIAGNOSTIC TESTS FOR SPECIALTY PHYSICIANS AND MEDICAL CENTERS IN THE U.S. AND OTHER INTERNATIONAL MARKETS"

Greg Richard
Chief Commercial Officer

Patient result reports reflect the updated information from the database. This enables physicians to identify optimal surveillance intervals and the patient's level of risk for progressing to cancer. With this database, the company empowers physicians to compare malignant and benign tumors when traditional cytology and other first line testing are uncertain.

Advanced Molecular Diagnostic Tests

The Interpace Diagnostics platform performs clinically beneficial molecular diagnostic tests to evaluate the risk of cancer and improve patient diagnosis and management. The company is focused on developing and commercializing molecular diagnostic tests for specialty physicians and medical centers in the U.S. and a number of international markets. These molecular tests enable healthcare providers to avoid unnecessary surgeries and better assess the risk of cancer progression in their patients while providing unparalleled accuracy and clarity to improve their patients' condition.

When a doctor reaches a state of uncertainty, he thinks of securing a second opinion through molecular testing which provides unparalleled insights to determine the likelihood of cancer. "We often serve as the "tiebreaker" by providing data at the molecular level. If the first line testing is equivocal, we help to answer the remaining questions and provide more clarity through the reports that are offered to our physicians," explains Greg Richard, Chief Commercial Officer, Interpace Diagnostics.

Interpace Diagnostics commercializes molecular tests for thyroid cancer, pancreatic cancer, lung cancer, and esophageal cancer. Its next-generation sequencing (NGS)-based mutation profile—ThyGeNEXT—locates mutations from thyroid

Team of Interpace Diagnostics

nodules that are highly indicative of thyroid cancer while ThyraMIR, a miRNA classifier, assists physicians in identifying the thyroid nodules that are least likely to be malignant. For the diagnosis and prognosis of cancer from pancreatic cysts and lesions, Interpace Diagnostics provides a unique, DNA-based, integrated molecular pathology test—PancraGEN—to help physicians manage each individual patient optimally. Recently, the company collaborated with a new customer, Piedmont Healthcare of Atlanta, to make PancraGEN available to the system's physicians.

For diagnosing lung cancer, the company has launched RespriDx, which enables physicians to determine whether neoplastic deposits represent metastases or a new primary lung tumor. Interpace Diagnostics also has a product for Barrett's Esophagus—BarreGEN—that allows physicians to identify the patients that are most susceptible to progressing to esophageal cancer. It enables more personalized management of the disease, including early intervention to decrease the possibility of progression to cancer. One of the unique characteristics of BarreGEN is that it is prognostic. In other words, using the data from Interpace Diagnostics' database, BarreGEN identifies the patient's mutational load and helps predict the likely timeframe for a patient to develop esophageal cancer. Hence, it not only helps the physician evaluate the patient's current status but predict his condition over a specific time period.

The Noteworthy Achievements

2018 has been a remarkable year for Interpace Diagnostics; the company has grown sequentially quarter over quarter. The company has flourished both in terms of test volume of its molecular tests as well as revenue. Recently, the company received coverage policies for its thyroid molecular tests from numerous Blue Cross BlueShield plans. Since the beginning of 2018 30 BlueCross Blue Shield plans have implemented favorable coverage policies for ThyGeNEXT and ThyraMIR.

The combination of ThyGeNEXT and ThyraMIR is the only test that includes rule-in and rule-out capabilities. The rule-in component utilizes next generation sequencing of the patient's DNA and RNA while the rule-out capabilities are driven by 10 distinct micro-RNA's, providing physicians with clinically actionable test results. Interpace Diagnostics has conducted over 25,000 thyroid molecular diagnostic tests for nearly 400 physicians and hospitals across the globe following its initial launch as ThyGenX, in 2014.

> "THE MOLECULAR DIAGNOSTICS TESTS ENABLE HEALTHCARE PROVIDERS TO AVOID UNNECESSARY SURGERIES AND BETTER ASSESS THE RISK OF CANCER PROGRESSION IN THEIR PATIENTS"

Earlier this year, Interpace Diagnostics replaced its initial mutational panel, ThyGenX, with ThyGeNEXT, a next-generation mutation panel. ThyGeNEXT includes a more comprehensive set of markers that not only identify malignant or benign nodules, but also ascertain their aggressiveness and other characteristics, providing physicians with incremental insights to assist in surgical decision making. It is offered with ThyraMIR for a subset of patients based on the results of the ThyGeNEXT test. Related to this unique combination assay, the company recently presented critical data from its Thyroid Registry observational study supporting Interpace's molecular tests at the American Thyroid Association (ATA) meeting held in October. The data showcased a real-world view of how physicians employ Interpace's thyroid assays and the degree to which they are helping physicians make appropriate decisions regarding surgeries. In the meeting, Interpace Diagnostics demonstrated its ability to take data from the test results and turn it into useful, actionable information for physicians. The data presented has been well received by physicians and further validates the company's novel combination testing platform.

Interpace Diagnostics has recently developed two distinct key opinion leader (KOL) groups, one each for its thyroid and gastrointestinal (GI) business units. The members of the KOL advisory boards are luminaries in their respective fields and many are part of key guideline committees such as the American Thyroid Association (ATA) and American Gastroenterological Association (AGA). The primary goal of this initiative is to seek input to inform our strategic planning process. With the support and guidance from these groups, Interpace looks forward to understanding the market, opportunities, and the optimal patient type in order to offer the best and most appropriate testing methods. Richard says, "We are now using "voice of the customer" to ensure we are aligned with the markets we serve." He also states, "Our customers and their patients expect and deserve innovative products and services that address unmet needs."

On the data and informatics front, Interpace Diagnostics has signed an agreement with a third-party that will help the firm to leverage the data from their testing databases. This third-party has started working with numerous pharmaceutical companies using Interpace Diagnostics' data to develop a companion diagnostic test for their therapeutics. For the first time, the company's database has manifested as a bioinformatics opportunity. "Until now we didn't know how to fully leverage or monetize the significant amount of data that we have accrued over the years. For the first time, we are working with a third-party that we believe knows how to utilize this kind of data for the diagnostic and pharma services industries," expressed Richard.

Interpace Diagnostics also has a robust pipeline comprised of new products and service enhancements. The company will continue to enhance the thyroid products to optimize performance and add any new markers that are discovered that offer incremental insights. In addition, the company is focused on Barrett's Esophagus, a rapidly growing condition affecting millions of people in the U.S. and a precursor to esophageal cancer. The company is constantly looking at opportunities to expand its molecular diagnostics capabilities related to Barrett's Esophagus and has soft-launched BarreGEN in certain markets. Simultaneously, Interpace Diagnostics is working on the clinical validation of BarreGEN and these study results will be published by one of the physicians who has used the test with his own patient population. The physician has collaborated with the molecular pathologists and R&D team at Interpace to review the patient data and analyze the results. His analysis of the results will be published in a peer reviewed publication in the first quarter of 2019, providing further evidence of the test's clinical utility. CA