THE WALL STREET TRANSCRIPT
Connecting Market Leaders with Investors

Interpace Diagnostics Group, Inc. (NASDAQ:IDXG)

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SECTOR — PHARMACEUTICALS

TWST: Interpace Diagnostics is a molecular diagnostic provider, but can you summarize the underlying technology and your lead commercial offerings?

Mr. Stover: We are a molecular diagnostics company that is focused on the somewhat novel space of pre-cancer, meaning we focus on biopsies that come back as indeterminate. What we mean by that is that there is no obvious cancer or a lack of clarity about what the biopsy really says, so these biopsies would then be reflex to us. We typically use a combination of biomarker analysis and, for our thyroid and endocrine assays, our novel microRNA analysis. For our pancreas and GI assays, we use a combination of biomarker analysis and evaluations, such as microsatellite instability and loss of heterozygosity.

Another way to look at this is to say that we do a deep DNA-based evaluation that includes the interrogation of specific biomarkers. As a pre-cancer company, we are truly a personalized medicine business. We can reveal to patients and physicians where an indeterminate biopsy and a precancerous lesion will be in five years, meaning whether or not a patient is going to progress to metastatic cancer or not. We are able to tell them with a high degree of probability where that patient is to help them direct therapy.

TWST: What is the sample type that is being used to assess the status of the patient?

Mr. Stover: Most of our samples come from fine needle aspirations known as FNAs. We also recently got an approval to do samples on cytology slides. Our two primary areas of focus are pancreatic cancer and thyroid cancer. We also have a smaller relatively new offering in lung cancer. Our pipeline product is a product called BarreGEN for Barrett's esophagus, which is the precursor to esophageal cancer.

TWST: The thyroid molecular tests that you provide include the first and only miRNA gene expression classifier on the market?

Mr. Stover: That is correct.

TWST: When the evaluation is done by the test, how accurate is it in identifying whether somebody has thyroid cancer?

Mr. Stover: There are really two components of accuracy known as negative and positive predictive value in assessing the accuracy of assays here. Negative predictive value, or NPV, is the probability that a patient will not progress to metastatic cancer, while positive predictive value, or PPV, is the probability that a patient will progress to metastatic cancer. From a differentiating factor in terms of who we are and what we do, we look at the competitive position of both NPV and PPV in our assays.

For thyroid, our combination of ThyGenX — and now ThyGeNEXT — which is an oncogene panel, and ThyraMIR, which is the microRNA classifier, looks at both NPV and PPV, whereby our NPV is greater than 94%, while our PPV has been determined to be greater than 54%. The largest company and competitor in the thyroid space has a product called Affirma, and while our NPV is roughly the same as the market leader, our PPV is stronger than theirs. So it is a strong competitive position for us.

TWST: How do you characterize your total addressable market? Where do you stand in terms of market penetration at this point?

Mr. Stover: We calculate the size of the addressable market as being the number of indeterminate biopsies reported in the U.S. market times roughly our price. Accordingly, the size of the thyroid market for us is roughly $350 million to $375 million. We use the same methodology to calculate the size of the pancreatic cancer market. We calculate that the size of the pancreatic cancer market is roughly a $300 million to $375 million market.

When you look at the size of the market today, we don't disclose what our individual units or dollars are for our specific products, but when we look at the size of the thyroid market, we know our biggest competitor has about $80 million in revenue, and we are less than $20 million. So the total addressed market today is likely around $100 million. Again, for thyroid, we know it is at least a $350 million market, so there is plenty of opportunity there.

Our ability to grow all of our markets is dependent on a number of things. First and foremost is reimbursement and guidelines and the quality of the guidelines. On reimbursement, if you don't have broad-based reimbursement support, the size of a market really doesn't matter as you have to get paid for the work you perform. The support of guidelines for molecular analysis certainly drives adoption.

As we look at our tests in terms of pancreatic and thyroid cancer, both of our tests are covered by Medicare. A majority of pancreatic cancer patients are Medicare-based patients. The majority of our thyroid patients are younger and not covered by Medicare, but we have strong coverage with private payers. We have a nice balanced approach in this area.

We do take business away from some of our competitors in thyroid, but most of our revenue growth comes from new customers. Certainly, in pancreatic cancer, virtually all of our revenue growth comes from new customers.

Overall, we have had some very good growth over the last couple of quarters. In fact, we have had six consecutive quarters of topline revenue growth. We have revenue growth from a combination of unit growth as well as improvement in reimbursement or price. That combination has been very supportive for us both in terms of our pancreatic assay and our thyroid assays as well.

TWST: In 2017, you had revenue of $15.9 million, which was a 21% increase from the previous year. Generally, could you break down that revenue composition?

Mr. Stover: In 2017, roughly half of our revenues came from PancraGEN and the other half from our thyroid business. In 2018, and going forward, we are seeing the largest portion of our growth coming from our thyroid business. However, our PancraGEN and our pancreas business is also growing both in terms of price and units. We do not currently provide a separate breakdown of sales dollars and units, but we may do so in the future now that all of our businesses recognize revenues on the full accrual basis as of the beginning of 2018 in accordance with generally accepted accounting procedures.

TWST: On the thyroid tests, the ThyGenX and ThyraMIR, are they done in combination with each other or for different patient populations?

Mr. Stover: ThyGenX is the biomarker assessment, and that is done initially. About 80% of the ThyGenX assays that are done reflex to ThyraMIR, and that percentage keeps growing. It is a matter of how much information you need. If ThyGenX is clear in terms of the potential outcome of this already indeterminate evaluation, the physician may be ready to stop and perform surgery or some other option, but most often, it is reflexed to our more detailed microRNA assay, ThyraMIR.

TWST: Often you hear this decoding of the genome hasn't reached its potential that scientists thought it would. I am assuming you might see the situation differently in that you see how a few markers are used in each test and reveal a lot. I wanted to give you an opportunity to say something about either the work that's gone on to develop these, or how a few signals or patterns allow us to know a lot about a person's health status.

Mr. Stover: What we do at Interpace is truly personalized medicine, and it is truly the future of medicine. Without the sequencing of the human genome, we would have no business. Effectively, cancer is a genetic disease. Although it is not exclusively genetic, it is largely genetic, so understanding the genetic makeup of a particular cancer and the patient and ultimately the therapeutic treatment is important to project, predict an outcome, and ultimately target and treat a patient and a specific disease state.

The combination, if you will, of both focusing on positive and negative predictive value, we believe, allows physicians and patients to know who is going to progress to cancer or who needs "active surveillance."

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TWST: Most people are familiar with how deadly pancreatic cancer is. Is there a large advantage to catching it early?

Mr. Stover: There is a large advantage to catching all cancer early, so that's really important. As we look at pancreatic cancer and the surgeries for it, what we realize is that somewhere between 60% and 80% of the surgeries for pancreatic cancer are unnecessary. Remember, we are only looking at biopsies that are indeterminate.

If you can imagine that you have a patient that has a high probability of pancreatic cancer, they go through CAT scans and other imaging procedures. Then, they do a biopsy, which is typically late in the process, and if the biopsy comes back as indeterminate, this is when it likely reflexes to us for molecular testing. In some cases, surgery would not be beneficial, meaning that the patient has a very aggressive form of cancer that surgery would simply not be helpful. In other cases, surgery should be actively pursued, and still in other cases, there would be no benefit of surgery. We are able to help make that determination.

The typical pancreatic surgery is called a "Whipple procedure" and is a very invasive, expensive and difficult procedure for surgeons to perform. It will also likely result in a limited beneficial outcome. We are able to provide both the patient as well as doctors critical and detailed information that is actionable.

By the way, the same situation applies to thyroid cancer and thyroid surgery. A sizable percentage of the thyroid surgeries are ultimately unnecessary. Accordingly, we are focused on reducing the cost of health care at a very early stage while at the same time improving the ability of physicians to better treat and serve their patients effectively and efficiently.

Just think about what happens in the case of pancreatic and thyroid cancer when a biopsy comes back and it is indeterminate. In the old days, what would you as a doctor or hospital system or you as a patient do? Do you move forward with a very aggressive surgery or not?

Today, we are able to really direct physicians with a high degree of probability regarding whether or not they should provide an aggressive intervention or not. It provides that at a very high level, although that is not the only kind of comparison and evaluation. What I mean by that is, while we are very much focused in the biomarker arena and the DNA arena for thyroid and pancreatic cancer, we also collect a great deal of data. The value of that data is becoming increasingly important to us and the pharmaceutical industry, as it is beginning to build products that require the information that we have, including targeting patients for clinical trials and preclinical assessments.

We have 10 years of data on pancreatic cancer patients. We have seven years of data on thyroid patients. So if I'm a pharmaceutical company and I'm building a therapy in that space, I'm looking to potentially identify patients for a clinical study that would be responsive to the kind of therapy I'm offering. What you are seeing is the consolidation, if you will, of therapeutics, devices and diagnostics, which I believe is the exciting promise and future of personalized medicine, especially with more and more prognostic tools, like Interpace, focused on identifying where a patient will be in the next five years.

TWST: You're looking at alterations in genes plus a type of genetic information, miRNA. It is interesting that you are leveraging both. Did you want to say anything about that?

Mr. Stover: I couldn't say it any better than you did. These

are the building blocks of life, and these are exactly the mechanics of what we are looking at. By the way, we mentioned it for thyroid cancer and pancreatic cancer, but we also launched a product RespriDx for lung cancer. It is a smaller market opportunity, but we launched RespriDx just recently. Our pipeline product called BarreGEN, for Barrett's esophagus, is a $1 billion to $1.5 billion market opportunity. Barrett's esophagus is a rapidly growing disease and a precursor to esophageal cancer, which is just as deadly as pancreatic cancer.

the origin of lung cancer. We utilize our test to risk stratify, rather than screen, an indication of a problem or concern. Once a lesion is identified, we are able to move into action and look at a biopsy. If the biopsy is clearly malignant or clearly benign, then our test is not indicated. However, if it's indeterminate, RespriDx testing — like our thyroid and pancreatic cancer assays — is appropriate. As an oncologist or a radiologist looks to treat this indication of lung cancer, their approach could be very different depending on the results of our RespriDx test.

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TWST: You were recognized as a top bioinformatics provider by a publication called *CIO Applications*. What are you doing with the data that you are collecting in your databases? How is the molecular diagnostics field changing, and what do you believe your role as a company is in these changes?

Mr. Stover: The recognition by this well-recognized industry magazine was interesting because it positioned us with some very large companies like Illumina. *CIO Applications* recognized that the utilization of bioinformatics is fundamental to algorithmic activity and, as previously discussed, an important building block for the pharmaceutical industry. Today, we have somewhere between five and 10 years of experience with 40,000 to 45,000 patient samples in our registry and databases. We are in the process now of evaluating, assessing and categorizing the data for utilization by the biopharmaceutical industry.

TWST: Do you get a sense of how to further profile patients, even within these cancer groupings like pancreatic, thyroid cancer, etc.?

Mr. Stover: We do. A good example of that is ThyGeNEXT, our next-generation assay where we effectively added a panel of aggressive biomarkers to our original ThyGenX assay. It is based on experience, meaning what we are seeing with our pathologists in the lab. This process is continuous for all the areas that we work in. It is a very interesting learning process that is based on the amount of data that you are able to collect and the quality of your data information systems.

TWST: Do you have clinical studies going on currently, and if so, what are you doing, and why?

Mr. Stover: Some of that is obviously proprietary; however, we have announced a relatively large study with our ThyGenX and ThyraMIR thyroid assays for data mining and bioinformatics with over 2,500 test results. We are doing clinical data mining for mutations and microRNA. We want to show this information has the ability to risk stratify. The results are strongly associated with these aggressive biomarkers.

Remember, too, that we are constantly seeking to gain additional reimbursement, which is largely based on study work that we do. As I mentioned before, Medicare covers our PancraGEN assay; however, it is not widely covered by private insurance companies, and so we have a prospective clinical study for PancraGEN as well as a registry clinical validation and utility study that is ongoing to evaluate not only our existing FNAs but also the solid pancreatic and biliary lesions.

TWST: RespriDx for lung cancer, is it currently available?

Mr. Stover: It is currently available and was launched during the fourth quarter of last year.

TWST: This is interesting because you're talking about genetic information that's able to differentiate patients with metastases and new lung primary cancer, so can this assess the stage that it's at?

Mr. Stover: This information is more about an association of

TWST: You recently purchased assets from Rosetta Genomics. What is this deal about, and what does it mean for the company going forward?

Mr. Stover: Rosetta Genomics was certainly a competitor of ours in the thyroid space. At the end of May 2017, Rosetta filed for Chapter 7 bankruptcy and, at the same time, recommended to their customers to send their biopsy samples to us because we had a relationship with Rosetta, and Interpace had been previously approved to evaluate slide biopsies, similar to Rosetta's Reveal product. We had been performing thyroid testing from slides but on a smaller scale. Then, we started getting calls from Rosetta customers saying that they had been directed toward us, so that initiated a much larger process whereby a majority of the Rosetta customers transitioned to Interpace.

In the last several weeks, we also finalized the acquisition of certain equipment and fixtures that were at Rosetta's Philadelphia lab. We are currently doubling the size of our Pittsburgh lab, and so the equipment was very opportunistic. We are also planning on expanding our New Haven, Connecticut, lab as well, so we are able to use some of the equipment in that location. But more importantly, as we have now grown and expanded this slide analysis in addition to our FNA analysis in thyroid, a good deal of the specific equipment from Rosetta was really very helpful to us. In addition to that, we also brought onboard a number of Rosetta's former employees that had extensive experience in this area. So far, this "acquisition" has been a very beneficial opportunity for us to especially expand our thyroid assay into the cytology slide market.

TWST: How would you characterize the company's laboratory structure and capabilities overall, and how do you work with hospitals or medical centers or clinics and so forth?

Mr. Stover: We are still a small but growing company with a little less than 80 people. We have about 30 people in the commercial side and approximately 30 people in operations actually processing slides and biopsies. The rest are administrative and reimbursement people. Our operations are performed in two CLIA, CAP-certified labs. Our major lab is in Pittsburgh, Pennsylvania, and we have a smaller lab in New Haven, Connecticut. Our headquarters is in Parsippany, New Jersey, where administration, sales and marketing, accounting and reimbursement, and business development is headquartered.

Of the 30 commercial people we have, we have 14 representatives in thyroid sales — endocrine — and 10 representatives in PancraGEN sales — gastrointestinal. In general, our sales and service reps are highly technical and very well-trained, and they reach out to potential customers that are individual physicians or physicians based in hospitals or medical centers. We have data that helps our sales and service representatives reach out to the right target customers.

I'm not sure if you know this, but Interpace was at one time part of a larger public company called PDI; PDI was a contract sales

and marketing organization, or CSO, in the pharmaceutical, device and diagnostics space. When Interpace sold PDI, we were able to maintain some of those commercial relationships as well as some of the data management systems and related software.

Interpace is different than many other molecular diagnostic companies. Our lead is really our commercial competency. We look for, acquire and integrate tests into our system. Our sales strategy is a combination of marketing and directly reaching out to sophisticated customers with our studies and experience and, of course, communicating with them through our customized professional reports. We also have an exclusive relationship with LabCorp, and they exclusively market our thyroid tests.

You have heard us talk about our desire and interest in the bioinformatics space in the pharmaceutical industry, and we are doing the development work in that space today. We want to be able to work more closely and confidently with pharmaceutical and biotech companies, which can be a whole new revenue source that has a different reimbursement risk profile than our molecular diagnostics business today. We believe we have a leg up on the competition here because we already have relationships in the pharmaceutical industry to draw on. Our vision is to also expand our BarreGEN assay with important partners.

As we look to expand even further, our goal is to first break the $20 million revenue level in 2018, and then, our next target will be $40 million in revenue in the near future. Today, we are still perceived as a small or a microcap company. We plan to convince institutional investors and supporters that we are a viable standalone business. For us, driving to cash-flow breakeven is a very important milestone in the near future as well.

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TWST: What are your operational and strategic objectives for the next year?

Mr. Stover: Let's talk about the remainder of 2018 as a place to begin, since we are three-quarters of the way through. Our goals for the remainder of 2018 are basically to continue our organic growth and expansion of both our thyroid franchise and PancraGEN — our endocrine franchise. In the second quarter of 2018, we expanded our guidance, announcing that we will do more than $20 million in net revenues for the year. We expect to fine-tune that in Q3.

From an operations point of view, we are continuing to drive our gross profit margins. Our last quarter gross profit was just shy of 60%. We believe we can cross over into the mid-60% range in terms of gross profit in the future with volume growth and automation.

From a reimbursement point of view, we have had a lot of success, especially in thyroid. In the first half of the year, we had 27 approvals from Blue Cross and Blue Shield for our thyroid assays alone, and we wish to continue that success. In addition to that expansion, the absorption of the Rosetta assets is critically important to us and ultimately fundamental to our continued growth.

As we look forward to 2019, we want to continue to expand our product base with improvements like we did in 2018 with ThyGenX — now ThyGeNEXT — and ThyraMIR. We plan to continue to move forward aggressively with BarreGEN as we seek partners, who have a similar vision, to work with us and help validate our assay. We hope to see growth in RespriDx because it has been a relatively new release.

We are looking for additional products to acquire that fit into our verticals of GI and endocrine franchises because we already have the sales and service representatives in place with doctor relationships and want to aggressively continue to expand our sales force. We plan to continue to progress with reimbursement to move from coverage to being on contract. We also will be looking to accelerate our progress with BarreGEN and begin to possibly monetize our databases that we have developed over the prior 10 years. That is a brief summary of the next 18 months or so and our plans.

TWST: What is the long-term vision for the company?

Mr. Stover: The long-term vision of the company beyond the next 18 months will result in us being a greater force in the molecular diagnostic space, and that is a core competency. We have ambitions to expand our testing, not just from a CLIA lab with CAP certification but toward products that require FDA approvals as well. Remember, we are a commercially based company, so we are always looking for new products to sell and market. We also have deep capabilities in the microRNA space, and we hope to develop those unique capabilities even further.

TWST: What should investors know about Interpace Diagnostics today if you had to summarize it?

Mr. Stover: This is a great question. What I'd say about Interpace today is that we are a relatively unknown company. We have been performing at an extraordinary rate on all fronts, and our goal is to continue to grow and expand. We have not only a unique position and a unique offering, but it is scalable as well. We have a strong balance sheet with no long-term debt and Medicare coverage for all products and strong reimbursement for our products with commercial payers as well.

We have a large pipeline of near-term product opportunities as well as for our products that are already developed. We are in an environment that is really the future of medicine, meaning we are a part of the future of personalized medicine. As medicine changes to be more prognostic along with earlier assessments, which it already is, it will continue to work to our advantage and opportunity.

TWST: Do you have anything else to add?

Mr. Stover: Our internal drivers include expanding reimbursement and securing additional contracts. We are increasing the size of our sales force and adding more clinical studies to assist our competitive position as well as help us to improve reimbursement. What I didn't mention is the expansion of our LabCorp contract to include Dianon as a provider of cytology services for our mutual customers. With the expansion of our lab space and the acquisition of the Rosetta assets, we have the people and the capacity to meet our plans of continuing to grow while continuing to manage our cash burn rate appropriately and rationally while we build to cash-flow breakeven.

TWST: Thank you. (KJL)

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