PixCell Planning 2021 US Launch for HemoScreen Test, Readying Sepsis Test

Aug 13, 2020 | Justin Petrone

NEW YORK – PixCell Medical is laying the groundwork for a full commercial launch of its point-of-care HemoScreen platform in the US while carrying out development of a new test panel for sepsis.

CEO Avishay Bransky said the Yokneam, Israel-based company has been working with early adopters in the US since it received US Food and Drug Administration clearance for its HemoScreen platform in 2018. The company has also seen uptake of HemoScreen in Europe and Australia since PixCell began selling the portable hematology analyzer in those markets.

PixCell has been collaborating with some early adopters at universities in the US as part of its prelaunch activities, but it is ready to begin selling more widely. "Next year we will launch in the US," Bransky said. "It's the largest market for point-of-care testing. Scandinavia and Western Europe are low-hanging fruit, but smaller markets," he remarked.

Bransky cofounded PixCell Medical in 2009, and though it has received a CE mark and FDA clearance for its HemoScreen platform in recent years, the company has worked to build up relationships in various markets before embarking on full commercial launches. PixCell currently employs 25 people, most of whom are based in Israel, Bransky noted, though it does have several people based in the US to support its pending launch there.

Its core application is providing a complete blood count, or CBC, at the point of care on an analyzer that contains all reagents necessary to carry out the analysis. A sample obtained from a blood draw is inserted into a disposable cartridge, which is processed within the benchtop instrument. The analyzer is built around microfluidic technology as well as imaging and artificial intelligence in an arrangement PixCell refers to as imaging flow cytometry. Thousands of cells are imaged quickly within the instrument and sorted using AI tools according to varying aspects.

"As opposed to standard hematology analyzers that use standard or electrical property measurements, we inspect thousands of images of cells in a manner similar to the gold standard, which is looking at the cells through a microscope," noted Bransky. After imaging and analysis PixCell's technology can "classify the different types of cells based on different properties, such as morphology, nucleus size, shape, and staining properties, which offers more information on a single cell than what is currently obtained by the current laser-scattering techniques," he said.

"Using the imaging and AI, you can differentiate between many types and subtypes of cells, and you are able to also enumerate and detect abnormal cells, which is not possible with even the highest level of fullblown analyzers," Bransky continued.

It is this attribute that has enabled the firm to expand its test offering, as the company can detect other markers of clinical utility in addition to measuring CBC. The company is adding immature granulocyte (IG) and monocyte distribution width (MDW) as part of its core CBC assay with improved algorithms, which will be rolled out as part of the next version of HemoScreen.

"We can now count abnormal cells," said Bransky. "It's extremely important to detect the slightest presence of these cells at an early stage because they are indicative of various blood cancers," he said.

The company is also looking to combine the additional markers procalcitonin (PCT) and C-reactive protein (CRP) in a future sepsis test, which will also carry out CBC, IG, and MDW analysis. Bransky said this multimarker approach could give the firm an advantage over other assays in use that only measure single biomarkers.

"They are not specific enough, they are not sensitive enough, each biomarker alone can't predict a certain type of infection at a certain stage of the disease," said Bransky. "It's agreed by all scientists that a combination of biomarkers is required and this, in fact, is what they do in large hospitals, they look at a variety of markers and symptoms and decide on what antibiotics to prescribe," he said.

He noted that MDW is used as a biomarker to indicate sepsis, as is IG, which is a marker for infection. PCT and CRP are also used to detect the presence of infection in a patient. By bundling all of these markers into one assay, the company hopes to have a test that will provide more information to clinicians and in a point-of-care setting. PixCell currently believes it could have this sepsis cartridge CE marked for use in Europe by next year, with an FDA clearance perhaps obtained in 18 months, indicating US clinical availability some time in 2022.

Bransky said that PixCell is interested in the antimicrobial resistance testing market because of both the clinical need, and the firm's ability to provide rapid diagnostics at the point of care.

"AMR is one of the greatest if not the greatest global health issue," said Bransky. "Some say that 50 percent of prescribed antibiotics were not supposed to be prescribed … because it was viral or because it was a bacteria that did not react to this type," he said. "One of the solutions is to have specific, immediate diagnostics."

It has certainly attracted interest from others. This month, HelixBlind, a Marlborough, Massachusetts-based company announced its intention to commercialize a rapid test for sepsis. And many test markers are taking part in a £10 million ($13 million) Nesta challenge called the Longitude Prize to develop assays, such as lateral flow tests, for antimicrobial resistance testing.

Down under and up north

While the company sets its sights on US market adoption and building out its menu, it has seen some early success in markets like Australia and in some of the Scandinavian countries. Bransky said that PixCell has sold more than 100 HemoScreen analyzers to partners in the Australian state of New South Wales and will also soon have customers up the coast in Queensland.

"Australia is a very relevant market because there are many communities where they don't have access to blood testing," said Bransky. "They have to fly the samples or drive four or five hours just to get the sample to a lab," he said. "So, there is a clear need there."

The firm's Danish and Swedish partners include Changing Cancer Care, an EU-backed project to treat oncology patients at home in the border region of Denmark and Germany, as well as Karolinska Institutet and Uppsala University in Sweden.

"They have tried the HemoScreen in the emergency room, primary care, and oncology settings," Bransky said, adding each represents a "major market segment" for PixCell and could benefit differently from having a point-of-care CBC test.

"Imagine you have a patient who has lost a lot of blood in the [intensive care unit], and the physician needs to determine whether to transfer blood, which is a valuable resource," he said. "Using HemoScreen they can make a more substantive, immediate decision."

To reach its European and Australian customers, PixCell currently relies on several distributors. The firm also now has a sales representative in Sweden, Branksy said.