



# Inex Innovate to Launch New Molecular Tests for Ovarian Cancer, Breast Cancer in Asia

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NEW YORK – The femtech market in Asia may be at its inception, but Inex Innovate wants to stake a claim. By 2021, the Singaporean molecular diagnostics firm envisions having multiple tests on the market, including two for ovarian cancer and one for breast cancer. The company's goal is to serve what it sees as a massive but underaddressed target group: Asian women.

"Health and medical products have historically been developed based on largely non-Asian populations," said CEO Kane Black. "With the democratization of genomic information, we know there is much genetic difference among various populations, hence solutions also need to be adapted," he said.

"In addition, due to the added complexity in regulatory roadmaps, women of child-bearing age are often excluded in the clinical validation [stage] of product development," he noted.

Black served previously as CEO of Nova Satra Dx, a Singaporean molecular diagnostics company with a focus on women's health. Last month, Nova Satra [merged with Inex Innovations and Exchange](#), another Singaporean diagnostics company, to form Inex Innovate. The deal was valued at \$72 million, and the company said it is eyeing a potential IPO on the Singapore, Hong Kong, or London stock exchanges by 2021.

Black said that investors are "increasingly taking note" of the efflorescing opportunity in femtech, though he conceded the Asian market is still "in its infancy." While Inex is an early player, Black said the market will likely see more competition soon. "We expect to see more companies come into the field in the coming years across Asia," he said.

Inex Innovate's predecessor companies, Inex Innovations and Exchange and Nova Satra, both had shown an interest in the women's and reproductive health markets prior to last month's merger. Founded in 2006, Inex Innovations and Exchange developed technology platforms with partners at the National University of Singapore (NUS) and Singapore's Agency for Science, Technology, and Research (A\*STAR). These included a rapid testing platform, prenatal health data analytics, and a circulating fetal cell extraction platform.

Inex through its subsidiary, the iGene Laboratory, introduced noninvasive prenatal testing in 2014. The company also developed OvaCis, an in vitro diagnostic kit for distinguishing between benign and malignant epithelial ovarian cysts.

Now, OvaCis will be the first new molecular test Inex Innovate will launch, according to Black.

The colorimetric assay can be used to assess ovarian cyst fluid for the presence of a protein



biomarker during an endoscopic cystectomy, he said. By providing a yes-or-no answer in a matter of minutes, Black said that OvaCis, "supports the on-site detection of ovarian cancer based on the presence of haptoglobin in the ovarian cyst fluid."

Haptoglobin in ovarian cyst fluid is a "highly sensitive biomarker for even early-stage ovarian cancer, with a high sensitivity," he added. The company has positioned the point-of-care test as an alternative to frozen section, which can take more than 45 minutes to complete. Black noted that OvaCis can also be used in settings where pathology facilities are not accessible.

The test has been CE-IVD marked since September 2016 and is currently undergoing clinical validation in Singapore and Malaysia, with similar studies planned for Hong Kong and Indonesia. OvaCis will first be launched in these countries in the next few months, Black said, followed by China and the rest of Asia.

NovaTect Bc, which was initially developed at Nova Satra, is the second diagnostic assay in Inex Innovate's pipeline. The test is a qualitative, blood-based test that relies on an epigenetic signature to stratify breast cancer patients. Nova Satra licensed Oxford Biodynamics' EpiSwitch technology for use in the test in 2017.

Black described the assay as a "patient-friendly, diagnostic option" that allows physicians and patients to reach a diagnosis quickly, while reducing the rate of false positives. "This allows patients and physicians to identify the presence of disease and make important treatment decisions sooner," he said. Inex Innovate intends to launch the assay by the second quarter of 2020.

The third test in Inex Innovate's pipeline is called Zena, which is targeted for a 2021 launch. Black described the test as an early detection blood test for women with a high risk of ovarian cancer. The test is based on a microRNA signature and has been validated in more than 700 clinical samples to date. Black said Inex is in the process of evaluating Zena in larger cohort studies. He claimed that Zena's miRNA signature will "be an improvement" over tests that rely on the protein marker CA125, which is considered to have a high false-positive rate.

## Expanding at home and abroad

Inex also continues to expand its non-invasive prenatal testing business. Inex Innovations and Exchange entered the market in 2014 with a cell-free DNA-based NIPT via its wholly owned subsidiary, the iGene Laboratory. The lab, now part of Inex Innovate, continues to offer iGene NIPT across Asia. The company received a license to offer the NIPT in Singapore [earlier this year](#) and Black said that the assay has sold well there.

In 2017, Inex also licensed from Singapore's Agency for Science, Technology, and Research a method to carry out NIPT using a [fetal cell-based approach](#) that relies on microfluidic technology. Black said that test is still in development.

All of Inex's tests are offered through the iGene Laboratory, which Black called "the vehicle to deliver innovations developed by Inex and Nova Satra Dx." The next-generation sequencing lab [was accredited](#) by the College of American Pathologists earlier this year.

He noted that the laboratory will also expand its operations to Bangladesh and Indonesia to reach more patients. Part of that expansion is a deal inked in late 2018 between the iGene Laboratory and Medinova Medical Services in Dhaka, Bangladesh to set up a joint molecular diagnostics lab for



women's health in that country. And this past May, it inked a similar deal with Klinik Fertilitas Bocah Indonesia to establish a new company, called PT Nexgen Diagnostika Indonesia, in Jakarta, the island country's capital, to offer molecular tests for women's and reproductive health.

"Indonesia and Bangladesh both have large unmet health needs," said Kane of the new deals. "This combined with high populations of 270 million and 163 million respectively, high birth rates, fast growing middle classes, and close proximity to Singapore make them both very attractive markets to enter," he said.

Looking ahead, Black said that Inex Innovate will continue to collaborate with NUS and A\*STAR on adapting detection technology platforms for clinical applications, such as the non-invasive and portable detection of protein biomarkers and the isolation of circulating fetal cells.

The company is also adding staff to its growing operations. It currently employs 19 but is adding more scientists, researchers, and product specialists to headcount. Black said that Inex aims to hire eight more people and expects its headcount to grow by 30 percent in the coming year.

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