

# Epigenomics

**Pharma & biotech**
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## Approaching the Chinese market

Epigenomics' partner BioChain reported positive results from a Chinese clinical study of its blood-based colorectal cancer test Epi proColon, indicating 74.8% sensitivity, non-inferior to the 68% for an approved faecal-based test. There is opportunity to gain early ground in China as incidence and awareness grows; the company estimates c 290 million people are eligible for testing. Meanwhile, the pending FDA approval decision is the key catalyst for the further recovery in the share price.

## CFDA clinical study data for Epi proColon

Epigenomics' partner BioChain reported data from its Chinese clinical study of the Epi proColon test from 1,074 patients in three centres. The data showed sensitivity of 74.8% (true positives) and specificity of 97.4% (true negatives) within the cohort, which included 300 colorectal cancer (CRC) sufferers. The Chinese approval application was submitted ahead of target, so the test could be on the market in 2015. Epigenomics is eligible for upfront and milestone payments plus royalties for Chinese approval and launch through BioChain.

## China a growing market

The incidence of colorectal cancer in China is rising and predicted to grow rapidly due to changes in diet and lifestyle, and the ageing population. Approved screening methods include colonoscopy and stool-based testing, but there is no centralised CRC screening policy in China. However, with the incidence rate growing at up to 5% per year, testing is becoming more widely available. Epi proColon could gain market share, particularly as it is a low cost, minimally invasive method.

## FDA approval decision for Epi proColon is key driver

Following submission of the FDA approval filing, Epigenomics remains confident that the data submitted support the approval application. A post-approval longitudinal study is being designed to demonstrate the long-term accuracy of Epi proColon. The US holds the key market potential given the government target to increase compliance from 60% to 80% and likely support for a blood-based rather than a stool-based test.

## Valuation: US approval decision is key catalyst

There is potential upside from the current EV of c €79m based on possible approval by the FDA. China is a high growth market providing additional commercial potential for Epi proColon.

### Consensus estimates

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/12	1.0	(12.0)	(1.3)	0.0	N/A	N/A
12/13	1.6	(7.3)	(0.6)	0.0	N/A	N/A
12/14e	4.2	(9.2)	(0.6)	0.0	N/A	N/A
12/15e	13.1	(8.4)	(0.5)	0.0	N/A	N/A

Source: Bloomberg

**Price** €7.0  
**Market cap** €95m

### Share price graph



### Share details

Code	ECX
Listing	Frankfurt
Shares in issue	13.5m

### Business description

Epigenomics is a German molecular diagnostics company focused on the early detection of cancer. Its main product is Epi proColon, a blood-based DNA test for colorectal cancer, which uses a sophisticated PCR assay to detect methylated copies of the Septin9 gene.

### Bull

- Size of Chinese population and with growing awareness and incidence of CRC.
- Opportunity to enter at an early stage of market growth in China.
- Growth in reimbursement for medical therapies in China creates demand for screening methods.

### Bear

- Lack of government CRC screening policy in China.
- Chinese market would not support high-priced testing.
- Uncertainty of the FDA decision.

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