

# Novacyt

Clinical diagnostics

28 April 2017

## Building momentum toward break-even

Novacyt reported FY16 results on 27 April. Headline sales announced in January showed that total FY16 sales grew 25% y-o-y to €11.1m (38% at a constant exchange rate, CER). The acquisition of Primerdesign (consolidated from May 2016) added to total group H216 sales, which grew an impressive 47% (68% at CER) y-o-y. Novacyt's earnings showed that sales growth was accompanied by a substantial expansion in gross margin from 48.1% in FY15 to consolidated 54.9% in FY16 or 59.0% pro forma. All this boosted consolidated EBITDA close to break-even at -€0.7m in H216 versus €1.6m in H116. We find the combination of a continuing high growth trend and near break-even EBITDA comforting and supportive for the share price.

### Primerdesign to lead the profitability

On a pro forma basis, Primerdesign's FY16 sales were £4.2m (€5.1m), constituting 46% of the total Novacyt revenues compared to £3.9m (€5.3m) in 2015. While still a recent acquisition, Primerdesign (innovative real-time qPCR equipment and consumables) is profitable with a gross margin consistently in excess of 80% and an EBITDA margin of 40% and we expect it to be one of the key growth drivers for Novacyt in the short term. Lab21 represents an established business within Novacyt with FY16 sales of £5.0m (€6.2m), a decrease of 8% at CER mainly due to a series of one-offs including lumpy tender awards, challenging emerging market conditions and a strong comparator period. Notably, Lab21's H216 sales were stronger by 7% at CER versus H116. NOVAprep's (innovative, proprietary liquid-based cytology platform) FY16 sales were €1.6m, up 24% y-o-y, with the Asia region growing the fastest at 116%.

### Outlook: Strong start in 2017

When discussing the outlook for 2017, management pointed to a strong start with Q117 sales growing 70% mainly due to a combination of Primerdesign acquisition and organic growth of NOVAprep (up 45% y-o-y) and Lab21 (up 15% y-o-y). Novacyt's distribution partner Cepheid aims to launch NOVAprep in the South American market after regulatory registrations are complete in H217, which could add to sales momentum.

### Valuation: Undemanding 1.1x price/sales

Based on the consensus sales estimates for 2017, a price/sales ratio of just 1.1x seems undemanding. Novacyt reiterated its intention for dual listing on AIM, albeit no specific timing was provided yet. 2017 could be transformational if Novacyt manages to achieve profitability, while Primerdesign's expansion into the clinical testing market (see below) is one of the most significant near-term catalysts.

#### Consensus estimates

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (c)	P/E (x)	Yield (x)
12/15	8.9	(13.2)*	(2.05)*	0.0	N/A	N/A
12/16	11.1	(5.7)	(0.47)	0.0	N/A	N/A
12/17e	15.2	(0.8)	(0.06)	0.0	N/A	N/A
12/18e	17.8	(0.4)	(0.03)	0.0	N/A	N/A

Source: Bloomberg. Note: \*A goodwill impairment of €9.8m was recorded in 2015.

Price €0.93

Market cap €16m

#### Share price graph



#### Share details

Code	ALNOV
Listing	Alternext
Shares in issue (includes €2.7m fund-raise in December 2016)	17.3m
Net debt (€m) at end-2016	3.4

#### Business description

Novacyt is a clinical diagnostics company that has developed innovative platforms, but is also offering more conventional laboratory products for an established client base. NOVAprep is an innovative, proprietary liquid-based cytology platform, while recently acquired Primerdesign offers novel, real-time qPCR devices and consumables. Lab21 offers more conventional laboratory products.

#### Bull

- Strong historical top-line growth, undemanding price/sales multiples.
- Primerdesign is a molecular diagnostics business in a rapidly growing market; expansion into the clinical use market will substantially increase the potential.
- Novacyt is contemplating a potential dual listing on the London Stock Exchange's AIM, which could increase liquidity and improve access to capital for its growth plans.

#### Bear

- Novacyt is yet to achieve profitability.
- The company is a player in the highly fragmented and competitive diagnostics market.
- Some dependency on the tendering process may cause volatility in revenues.

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## **Primerdesign moves into clinical testing market**

Acquired in May 2016, Primerdesign is a UK-based molecular diagnostics company that has developed and commercialised a real-time qPCR system called genesis and sells proprietary molecular assays. It has developed a catalogue of around 500 molecular tests so far to academic and industrial customers in over 100 countries. Novacyt repeated its determination to invest in Primerdesign and expand its offering to clinical diagnostics market. The company mentioned that first five CE-marked assays are underway with the first one (Zika virus) expected to be launched in Q217. Currently, all Primerdesign tests are sold in the research use market; however, after the acquisition, Novacyt identified around 10% of molecular diagnostic tests in Primerdesign's current catalogue as suitable to be 'upgraded' for clinical use (approved as CE-marked *in vitro* diagnostics). According to the company, this could be achieved over the next five years, and while it is too early to estimate a precise effect on sales, this would likely substantially add to both sales volumes and margins. This is also one of the key rationales for the acquisition and investment in Primerdesign.

## **NOVAprep – rapid geographical expansion**

NOVAprep is marketed as a next generation liquid-based cytology (LBC) system and includes innovative LBC diagnostic equipment and consumables predominantly for cervical cancer screening (higher sensitivity and specificity alternative to Pap smear tests). NOVAprep is still in the early stage of commercialisation and FY16 revenues constituted a relatively small (14%) portion of total company sales, but this is one of the innovative platforms in Novacyt's portfolio growing at a double-digit percentage rate y-o-y. While the system was CE-marked in 2008, Novacyt announced the FDA clearance of the vial as Class I device (consumable part of the system) in February 2017, which could unlock new revenue source in the near future. Currently, Novacyt is seeking a US distributor. Geographical expansion is at the core of the marketing strategy for NOVAprep, therefore Novacyt continues working with distributors and launching the system in new territories with 10 new markets added in 2016.

## **Lab21 – back to sales growth in H216**

A notable development in Novacyt's established, profitable laboratory diagnostics products business was the return to growth in H216 underpinned by the expansion of the product portfolio and the launch of the offering in new markets. Lab21 mainly focuses on infectious diseases and oncology, has a broad client base covered by more than 300 distributors, also employing a direct salesforce in the UK. In FY16 Lab21's sales constituted 56% of total Novacyt sales.

According to the most recent news, Lab21 signed an agreement with MDxHealth, which grants Lab21 a non-exclusive licence to distribute MDxHealth's innovative, non-invasive, urine-based liquid biopsy test for prostate cancer (SelectMDx) in the UK. According to MDxHealth, the test has a negative predictive value of 98% for clinically significant disease, helps to reduce unnecessary expensive MRI scans and invasive prostate biopsies by approximately 50%. As an innovative, liquid biopsy test SelectMDx will be a standout in Lab21's portfolio. SelectMDx is MDxHealth's second prostate cancer test launched recently; therefore, it is too early to judge commercial success. However, the sales of MDxHealth's first prostate cancer test ConfirmMDx (tissue-based methylation test) grew from \$16m in 2015 to \$25m in 2016 in its fourth year in the market.

## **Strong start points to further growth in 2017**

In the outlook section of the results presentation Novacyt highlighted that positive sales momentum extended into Q117 (see above). While the company did not provide guidance for the full 2017, should the trends of sales growth and improving profits continue in the year, this could unlock upside in the share price, in our view. Novacyt's cash position was €2.9m at end-2016 and another €1.5m was added in debt in April 2017.

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