BRYAN, GARNIER & CO

Healthcare

8th August 2019

DBV TECHNOLOGIES

Healthcare
Biotech

BUY - TOP PICKS

Fair Value	EUR46(+174%)
Share price	EUR16.23
EPS 3Y Cagr	NM

Viaskin peanut (re)filed with the FDA … 60-day clock starts ticking

Timely refiling of Viaskin peanuts with the FDA

DBV has announced the refiling of Viaskin peanut (4-11yo) with the FDA. This refiling is very timely since the company announced earlier this year that it was expecting to refile the product candidate during Q3. Note that under the leadership of the new CEO, Daniel Tasse, the company withdrew the BLA for Viaskin peanut in December 2018. Since then, the team led by Julie O'Neil has been working on addressing the FDA's 17 observations, primarily focused on quality control and manufacturing leading to the achievement of today's milestone.

60-day clock now ticking!

Now that Viaskin peanut has been (re)filed, the FDA has 60 days i.e. until mid-October, to decide whether to accept the filing and start the review process of Viaskin peanut (VP) or issue a 'refuse to file/review'. Considering the efforts that have been deployed, we see the former more likely.

Free upside on potential priority review

Under the standard review timeline, the FDA has 12 months to review Viaskin peanut. However, it should be noted that the product benefits from the FDA's Breakthrough therapy and Fast Track designations making it eligible to the priority review (6 month review). While Aimmune Therapeutics' (AIMT) lead product, AR101, was also eligible for priority review, the FDA decided not to shorten the timeline. As such, we are sticking to a standard, 12-month review process, leaving a potential priority review as upside to our timing estimates for approval and launch (H2 2020). We see Viaskin Peanut reaching the market c.9months after AR-101, should the latter be approved.

AR-101 AdCom (13th Sept.) should assert VP's competitive profile

The AdCom for AR-101 will be held on 13th September, before the FDA's decision on whether to accept the filing for Viaskin peanut. We would anticipate the AdCom to focus on the safety profile of AR101 and be challenging for AIMT. While we believe the AdCom should recommend the approval of AR101, it would not be surprising to also recommend for a REMS, which is likely to affect the ramp-up of the product once accepted (FDA's decision expected in early 2020).

Market Data

Bloomberg / Reuters	DBV FP/DBV.PA
Market Cap.	EUR587m
E.V.	EUR467m
Free Float	55,3%
Avg. Daily volume (6m)	273.6
12m high / low	EUR42.0 / EUR7.7
Ytd Perf.	53.0%

EURM	12/18	12/19e	12/20e	12/21e
Sales	14.5	8.6	64.5	323.7
% Change		*-40.7%*		
EBITDA	-165.2	-173.0	-103.0	121.8
% Change		*-4.7%*	*40.5%*	*NS*
EBIT	-166.2	-173.2	-104.0	116.9
% Change		*-4.2%*	*39.9%*	*NS*
Net Income	-166.1	-173.2	-104.0	116.9
% Change		*-4.3%*	*39.9%*	*NS*
ROE	-1.37	-8.57	1.24	3.53

	12/18	12/19e	12/20e	12/21e
EV/Sales	32.1x	66.1x	10.5x	1.8x
EV/EBITDA	NS	NS	NS	4.7x
EV/EBIT	NS	NS	NS	4.9x
EPS	-5.74	-4.79	-2.88	3.23
% change		*16.6%*	*39.9%*	*NS*
P/E	NM	NM	NM	5.0x
Div Yield	NM	NM	NM	6.2%

Next Catalyst: AR-101 AdCom on 13th September

Last FV Change:

2018-12-20, Few details on resubmission timeline following BLA withdrawal

Last Reports:

2019-8-1, DBV TECHNOLOGIES (BUY - Top Picks, FV EUR46) | H1 results; Dense upcoming newsflow

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BRYAN, GARNIER & CO

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BUY ratings 47,9% NEUTRAL ratings 45% SELL ratings 7,1%

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