Medivation

A Look at the Growth and Share in Prostate Cancer

Both Zytiga and Xtandi 4Q sales are out. What do they imply?

Medivation's partner Astellas announced Xtandi US sales of \$126m (consensus: \$121m, UBS: \$124m) and OUS sales of \$38m (consensus: \$20m, UBS: \$28m), both coming in above expectations. Here we look at what the entire class (Xtandi + Zytiga) is doing in actual reported sales, the growth of the segment, and the relative dollar market share trends. The sales data suggest that [1] the market for androgen receptor (AR) antagonists is robust and growing nicely, contrary to the bear case on AR market size; [2] Xtandi continues to rapidly gain market share despite operating with a limited label compared to Zytiga, and [3] estimates should continue to rise over time.

Analysis #1: AR market annualizing to \$2.6bn, but still early in the game

Separately, JNJ reported upside Zytiga 4Q US sales of \$211m, and WW sales of \$495m (Street \$453m). Taken together, the no-longer nascent US market is now \$338m (annualizes to \$1.35bn), and is growing 98% y/y and 8% q/q. The OUS market is \$322m (+115% y/y, +18% q/q), and WW AR sales are now \$660m (annualizes to \$2.64bn), growing at 106% y/y and 13% q/q. The US growth reflects only minority penetration into the larger pre-chemo CRPC segment (where Zytiga alone is FDA-approved). Doc feedback suggests that barriers to pre-chemo utilization will erode with time (and Xtandi availability). OUS, the AR market is pulling even with the US mainly on the smaller post-chemo market (Zytiga pre-chemo approval in 2013). Hence, we see significant growth still to come with utilization in pre-chemo likely higher than post-chemo, longer durations of therapy, and ultimately, utilization further upstream.

Analysis #2: Xtandi market share gains, despite post-chemo label

In terms of market share, Xtandi gained another 300bp of US market share this quarter (now at 38%), and globally has gained 440bp share to 25%. We model Xtandi taking majority share in pre-chemo patients treated in 2016, but based on the well-received PREVAIL data at ASCO-GU, we see upside to share and sales estimates 2014-15.

Valuation: Buy, \$93 PT by DCF

Our model excludes hormone-naïve prostate, breast cancer, and acquisition premium.

Equities

Americas Biotechnology

12-month rating Buy
12m price target US\$93.00

Price US\$74.91

RIC: MDVN.O BBG: MDVN US

Trading data and key metrics

US\$84.29-42.63 52-wk range Market cap. US\$5.61bn Shares o/s 74.8m (COM) Free float 90% Avg. daily volume ('000) 1.186 Avg. daily value (m) US\$82.3 Common s/h equity (12/13E) US\$0.24bn P/BV (12/13E) 23.4x Net debt / EBITDA (12/13E) 11.6x

EPS (UBS, diluted) (US\$)

	12/13E	
	UBS	Cons.
Q1	(0.36)	(0.36)
Q2	(0.06)	(0.07)
Q3	(0.18)	(0.18)
Q4E	(0.19)	(0.09)
12/13E	(0.80)	(0.69)
12/14E	0.72	1.29
12/15E	4.69	3.87

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Highlights (US\$m)	12/10	12/11	12/12	12/13E	12/14E	12/15E	12/16E	12/17E
Revenues	63	60	182	246	417	832	1,248	1,571
EBIT (UBS)	(33)	(43)	(26)	(40)	77	428	793	1,077
Net earnings (UBS)	(34)	(39)	(41)	(60)	59	396	512	697
EPS (UBS, diluted) (US\$)	(0.50)	(0.56)	(0.52)	(0.80)	0.72	4.69	5.93	7.88
DPS (US\$)	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Net (debt) / cash	208	145	296	461	591	1,002	1,549	2,285
Profitability/valuation	12/10	12/11	12/12	12/13E	12/14E	12/15E	12/16E	12/17E
EBIT margin %	-52.4	-71.1	-14.4	-16.1	18.5	51.4	63.6	68.6
ROIC (EBIT) %	18.1	25.0	14.3	17.9	(32.0)	(169.7)	(335.2)	(477.5)
EV/EBITDA (core) x	-9.5	-15.2	<-100	<-100	64.9	10.8	5.1	3.1
P/E (UBS, diluted) x	(15.4)	(20.7)	(84.1)	(93.7)	NM	16.0	12.6	9.5
Equity FCF (UBS) yield %	1.5	(11.0)	(1.7)	(1.2)	1.6	6.4	8.8	12.0
Net dividend yield %	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Source: Company accounts, Thomson Reuters, UBS estimates. Metrics marked as (UBS) have had analyst adjustments applied. Valuations: based on an average share price that year, (E): based on a share price of US\$74.91 on 03 Feb 2014 11:13 EST

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Investment case

Our Buy rating on MDVN is two-fold: [1] positive data from the phase-3 PREVAIL study has removed a major risk of the stock [2] once data are available the stock becomes more broadly ownable, as the binary risk to the stock will have been eliminated. We see upside risk to Xtandi consensus peak sales, although we believe the rate of Xtandi growth will be debated. Big picture, we believe Xtandi is poised to become part of the standard of care in metastatic prostate cancer, and a positive trial will expand the opportunity beyond the post-chemotherapy setting where it is already approved. We think potential litigation risks and pre-chemo launch concerns will be overshadowed if data are sufficiently positive, and believe shares will move higher on the data.

Upside scenario

Our upside scenario of \$140 is driven by use in non-metastatic patients based on positive results from STRIVE and compendia trials. It also includes: [1] longer treatment duration for Xtandi, with patients in the pre-chemo setting receiving as many as 18 cycles of treatment on average. [2] Higher adoption assuming a strong survival advantage in PREVAIL.

Downside scenario

Our downside scenario of \$65 reflects limited adoption in the pre-chemo setting vs. the lower-priced Zytiga.

Upcoming catalysts

1) Data from the phase-1/2 breast cancer study. The company has started dosing patients in the second part of the study, making the first data (mostly safety) likely available this year (potentially ESMO). 2) Clarity on additional label expansion opportunities such as the MO and hormone naïve trial design and timing.

12m price target

US\$93.00

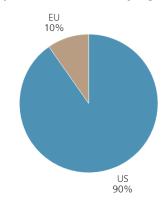
Business description

Medivation is a commercial-stage biotech company that developed and markets Xtandi (enzalutamide) for the treatment of metastatic castration resistant prostate cancer. The company is partnered with Astellas for Xtandi with significant milestones and tiered double-digit royalties for ROW sales. The key value driver, Xtandi, is a second-generation antiandrogen drug currently approved for the treatment of prostate cancer patients after progression on chemotherapy. The phase 3 PREVAIL study evaluating Xtandi in chemotherapynaïve patients would allow label expansion to a bigger population.

Industry outlook

While we expect large cap biotech to continue positive momentum on strong earnings growth, the smid cap universe will continue to be very data-driven, and to be tightly correlated to market risk appetite. Many mid-cap names have gotten credit for pipeline optionality during the recent biotech rally, although we note the laser-like strategic focus by management on PREVAIL has left the MDVN pipeline highly levered to Xtandi success. Following PREVAIL we expect management to disclose earlier pipeline programs, which in our view should we well-received and more closely align MDVN with the group.

Major Product Revenues by region (%) (2015)



Revenues by segment

Segment Revenues (\$m)	2011	2012	2013E	2014E	2015E
Oncology	60	182	248	417	761
Total	60	182	248	417	761

Source: Company data, UBS estimates