Prostate Cancer

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COMMENT

Implications of Zytiga's Pre-Chemo Approval

- **JNJ's Zytiga received pre-chemo approval on December 10th (see our note "Zytiga pre-chemo approved: still no OS").** There was considerable speculation as to whether Zytiga would hit OS significance with data updated since its presentations at ASCO and ESMO this year. We fully expected FDA to approve Zytiga for pre-chemo use even without statistically significant OS data, as was indeed the case. Notably, the label does include an update to the OS data, but statistical significance was not achieved.
- **Overall survival looks incrementally worse for Zytiga – which is good for Xtandi -- though we don't think it changes how the products will be used.** The OS difference was only 5.2 months, which is lower than what we (and probably most) were expecting. This missed significance with a p-value of 0.0151 (Exhibit 1). The placebo arm also saw median OS increase to 30 months, worsening the HR from 0.75 to 0.79. (Exhibit 2). The data is a little puzzling, but between the strong OS trend, the robust rPFS data (HR of 0.43 on a median treatment duration of 14 months) and the robust OS benefit in the "301" trial, we don't think the update changes Zytiga's profile all that much or even how it is likely to be used.
- **The tolerability profile looks similar to what was seen in the "301" trial.** As was the case in the "301" trial, Zytiga is associated with liver function abnormalities in the pre-chemo setting, underscoring the importance of regular LFT monitoring, as has been outlined in the label (Exhibit 3). Cardiac failure was also higher with Zytiga (now 2.1% vs 0.7% on placebo). And, of course, with the approval in the pre-chemo setting, Zytiga is tied to longer-term use of prednisone (all adverse events from the label are shown in Exhibit 4).
- **The approval now marks the first meaningful entry into the urology segment of the prostate cancer market since DNDN's Provenge.** As per JNJ's Q3 call, about 30% of Zytiga has been in the pre-chemo setting (the setting for which Zytiga was just approved), but uptake by urologists has been negligible, at least per IMS data. With this approval, we now expect a more significant push into the urology segment of the market.

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- **While MDVN (OP, TP: $73) is not disclosing how it might change its own statistical plan for its pre-chemo "PREVAIL" trial, the company is confirming that it will wait for OS.** This is in-line with our expectations and, frankly, makes sense, given that (1) Xtandi has a relatively long patent life (2) it offers the potential for an OS comparative advantage vs Zytiga, especially if that product goes off-patent in around four years and (3) makes market entry for downstream competitors all the more challenging. Our best guess is that PREVAIL is likely to report out in 2H'13 – and we expect positive results from that trial.
- **Assuming PREVAIL is positive, National Comprehensive Cancer Network (NCCN) guidelines likely will put Xtandi ahead of Zytiga.** As we noted in our email on December 5th ("NCCN Prostate Cancer Guidelines Updated: Allows for Xtandi Pre-Chemo Use"), Xtandi received in the pre-chemo setting a category 2a ("lower-level evidence"), which is the same as Zytiga, despite the "302" data results (both products are category 1 ("high-level evidence") in the post-chemo setting). Assuming PREVAIL is positive on OS, we would expect Xtandi to move to "1" – the same as Provenge – while Zytiga is likely to remain where it is.
- **We are not changing our Xtandi forecasts at this time.** Between what we see as more favorable tolerability and safety, the lack of required prednisone and likely better OS data, we continue to believe that Xtandi will capture a larger portion of the post and pre-chemo markets (we model 70% market share going to Xtandi vs Zytiga). We continue to believe that PREVAIL will show a treatment duration of at least the 14 months seen in the Zytiga "302" trial, resulting in upside from current levels.
- **For DNDN (N, TP: $4), the Zytiga approval marks the imminent entry of a competitor in the pre-chemo (urology) setting.** But overall, the timing and nature of the approval is in-line with our expectations. Last quarter saw a substantial decline at the academic setting (-25%) and we don't think this approval and label is likely to change that one way or another. We continue to believe that Provenge can be used in a niche setting of the mCRPC market – i.e. very slowly progressing asymptomatic mCRPC patients – although it remains to be seen what percentage actually fits into this category. Crucial for Provenge's future will be for DNDN to finally gain a foothold within the community (and especially community urology) setting and JNJ's push here won't make it any easier for DNDN. We are not changing estimates at this time – we forecast flattish revenues in 2013 overall vs 2012, with some growth thereafter.
- **For JNJ (N, TP: $71):** the Zytiga overall survival data is a slight disappointment, however, our (post-2014) Zytiga forecast already implies a competitive benefit for Xtandi secondary to not requiring prednisone on board. The smaller than expected OS benefit now leaves room for Xtandi to have a competitive benefit greater than already projected once PREVAIL reads out in 2H'13. In-line with this, a key element of our Neutral rating on JNJ is predicated on the fact that we expect notable competition to emerge for several key therapeutic areas in the next 12 months, keeping the stock range bound.

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Exhibit 1: OS Data from Label and as Presented at ASCO 2012

Approved Label			Data Presented at ASCO - June 2012		
Overall Survival	Zytiga (N= 546)	Placebo (N=542)	Overall Survival	Zytiga (N= 546)	Placebo (N=542)
Deaths	200	234	Deaths		
Median Suvival	35.3	30.1	Median Suvival	NR	27.2
p-value	0.0151		p-value	0.0097	
Hazard Ratio	0.792		Hazard Ratio	0.75	

Source: Company data, Credit Suisse estimates

Exhibit 2: OS Curves – From Label (Updated Data) and at ASCO

	0	3	6	9	12	15	18	21	24	27	30	33	36
Zytiga-updated	546	538	524	503	482	452	421	393	333	175	68	15	0
Placebo-updated	542	534	508	492	465	437	400	361	283	153	67	9	0
Zytiga-ASCO	546	538	524	503	482	452	412	258	120	27	0	0	
Placebo-ASCO	542	534	509	493	465	437	387	237	106	25	2	0	

Source: Company data, Credit Suisse estimates

Exhibit 3: Liver Function Abnormalities From Label

	"301"		"302"	
	All Grades	Grade 3-4	All Grades	Grade 3-4
High ALT	30.6	2.1	41.9	6.1
High AST	11.1	1.4	37.3	3.1
Total	**41.7**	**3.5**	**79.2**	**9.2**

Source: Company data, Credit Suisse estimates

Exhibit 4: Zytiga AEs from Approved Label

	Zytiga - "301"			Zytiga - "302"	
	All Grades	Grade 3-4		All Grades	Grade 3-4
Joint Swelling/discomfort	29.5	4.2	Fatigue	39.1	2.2
Muscle Discomfort	26.2	3.0	Edema	25.1	0.4
Edema	26.7	1.9	Pyrexia	8.7	0.6
Hot flush	19.0	0.3	Joint swelling/discomfort	30.3	2.0
Hypertension	8.5	1.3	Groin pain	6.6	0.4
Diarrhea	17.6	0.6	Constipation	23.1	0.4
Dyspepsia	6.1	0.0	Diarrhea	21.6	0.9
Urinary tract infection	11.5	2.1	Dyspepsia	11.1	0.0
Upper respiratory tract	5.4	0.0	Hot flush	22.3	0.2
Cough	10.6	0.0	Hypertension	21.6	3.9
Urinary frequency	7.2	0.3	Cough	17.3	0.0
Nocturia	6.2	0.0	Dyspnea	11.8	2.4
Fractures	5.9	1.4	Insomnia	13.5	0.2
Arrhythmia	7.2	1.1	Contusion	13.3	0.0
Chest pain or chest discomfort	3.8	0.5	Falls	5.9	0.0
Cardiac failure	2.3	1.9	Upper respiratory tract	12.7	0.0
			Nasopharyngitis	10.7	0.0
			Hematuria	10.3	1.3
			Rash	8.1	0.0

Source: Company data, Credit Suisse estimates

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Companies Mentioned *(Price as of 10-Dec-2012)*

Dendreon Corp. (DNDN.OQ, $5.04, NEUTRAL[V], TP $4.0)
Johnson & Johnson (JNJ.N, $70.6, NEUTRAL, TP $71.0)
Medivation (MDVN.OQ, $55.33, OUTPERFORM[V], TP $73.0)

Disclosure Appendix

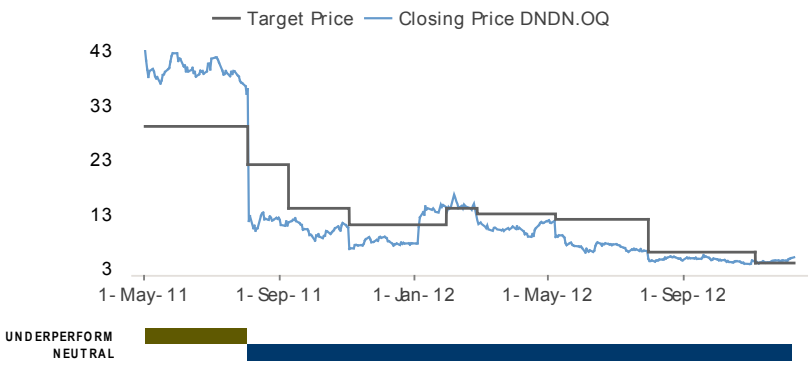
Important Global Disclosures

Lee Kalowski, Catherine J. Arnold, Ravi Mehrotra PhD, each certify, with respect to the companies or securities that the individual analyzes, that (1) the views expressed in this report accurately reflect his or her personal views about all of the subject companies and securities and (2) no part of his or her compensation was, is or will be directly or indirectly related to the specific recommendations or views expressed in this report.

Price and Rating History for Dendreon Corp. (DNDN.OQ)

DNDN.OQ	Closing Price	Target Price	
Date	(US$)	(US$)	Rating
02-May-11	42.81	29.00	U *
03-Aug-11	35.84	22.00	N
09-Sep-11	11.42	14.00	
03-Nov-11	6.55	11.00	
30-Jan-12	14.17	14.00	
27-Feb-12	11.81	13.00	
08-May-12	8.75	12.00	
31-Jul-12	4.76	6.00	
05-Nov-12	4.17	4.00	

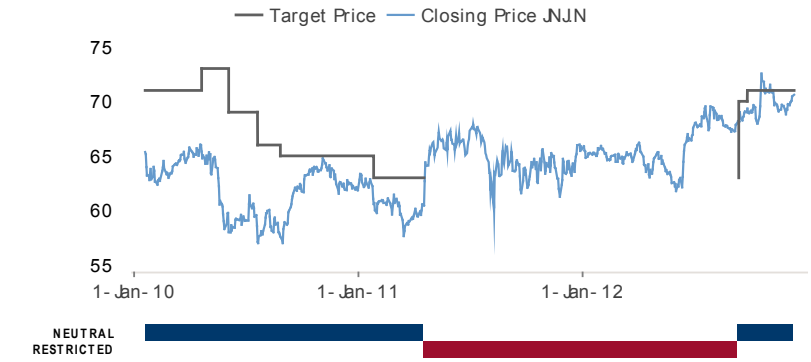
** Asterisk signifies initiation or assumption of coverage.*



Price and Rating History for Johnson & Johnson (JNJ.N)

JNJ.N	Closing Price	Target Price	
Date	(US$)	(US$)	Rating
19-Jan-10	65.35	71.00	N
21-Apr-10	65.39	73.00	
04-Jun-10	58.01	69.00	
21-Jul-10	57.12	66.00	
27-Aug-10	57.60	65.00	
26-Jan-11	60.60	63.00	
18-Apr-11	60.46		R
11-Sep-12	68.20	70.00	N
25-Sep-12	69.32	71.00	

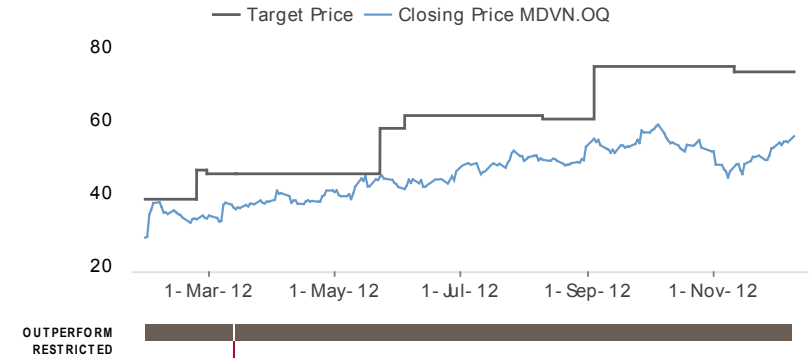
** Asterisk signifies initiation or assumption of coverage.*



Price and Rating History for Medivation (MDVN.OQ)

MDVN.OQ	Closing Price	Target Price	
Date	(US$)	(US$)	Rating
30-Jan-12	27.44	76.00	O *
24-Feb-12	32.50	92.00	
29-Feb-12	32.76	90.00	
13-Mar-12	35.70		R
14-Mar-12	35.28	90.00	O
23-May-12	44.17	115.00	
04-Jun-12	40.82	122.00	
10-Aug-12	48.85	120.00	
04-Sep-12	54.60	149.00	
11-Nov-12	45.70	73.00	

** Asterisk signifies initiation or assumption of coverage.*



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Price Target: (12 months) for Dendreon Corp. (DNDN.OQ)

Method: Our $4 target price for DNDN is derived from a discounted cash flow modeled to 2020 using a terminal growth rate of -5% and a discount rate of 10%.

Risk: Upside risk to our $4 target price include an accelerating launch trajectory, greater realized cost cutting than we model and successful commercialization in the EU; downside risk include: a launch trajectory below our expectations, greater competition than we anticipate and a higher cost base than we currently model.

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