D. Western Therapeutics Institute | 4576

Sponsored Research
February 14, 2023

Sessa Investment Research

Deployment of R&D expense going into full swing as late-stage US clinical trials for H-1337 get underway

RESULTS SUMMARY

- DWTI announced FY22/12 4Q consolidated financial results at 15:30 on Monday 2/13, and it plans to livestream via ZOOM a results briefing at 13:30 on Friday 2/17. After successful completion of the roughly ¥1.8bn financing last summer, the key takeaway is the Company is budgeting ¥1.5bn R&D expense for FY23/12 as multiple pipeline development projects go into full swing. According to the results briefing materials, main uses of R&D expense in FY23/12 include: 1) late stage Phase 2b clinical trials for H-1337 in the US, 2) development cost In Japan for DWR-2206 regenerative medicine cell-therapy treatment for bullous keratopathy (jointly developed with ActualEyes) and 3) a milestone payment on approval of DW-5LBT.

- On October 4, DWTI reached an agreement with the US FDA on the details for an additional study to be conducted on DW-5LBT, a new type of lidocaine patch for treatmFY22/12ent of neuropathic pain (jointly developed with MEDRx). On January 17, DWTI announced that results of the additional study were favorable, and that it plans to resubmit the application for approval in the 1H of 2023, and to receive approval in the 2H of 2023 after a 6-month review period.

- On December 16, DWTI announced that it has submitted an Investigational New Drug (IND) amendment to the US FDA to commence late-stage Phase 2b clinical trials for H-1337 glaucoma and ocular hypertension treatment. H-1337 has strong prospects as "first choice as a second-line Glaucoma drug" for patients who do not respond to PGs, and those who suffer side effects from multiple drug regimens. DWTI estimates the target market up to a maximum 40% of the estimated US market of $3 billion.

DWTI FY22/12 Consolidated Financial Results Summary and FY23/12 Initial Forecasts

JPY mn, % [J-GAAP]	FY18/12 act	FY19/12 act	FY20/12 act	FY21/12 act	FY22/12 init CE	FY22/12 rev CE	FY22/12 act	FY23/12 init CE
Net sales	**293**	**581**	**356**	**414**	**370**	**440**	**448**	**400**
YoY	***15.3***	***98.2***	***(38.7)***	***16.5***	***(10.7)***	***6.2***	***8.1***	***(10.7)***
Cost of sales	14	26	17	20			28	
Gross profit	279	555	339	394			421	
SG&A expenses	1,066	437	604	566			726	
• R&D expense	**795**	**249**	**351**	**316**	**790**	**NA**	**470**	**1,500**
as % of net sales	*271.5%*	*43.0%*	*98.6%*	*76.3%*	*213.5%*		*104.8%*	*375.0%*
• Other	270	188	254	250			257	
Operating profit (loss)	**(786)**	**117**	**(266)**	**(172)**	**(690)**	**(400)**	**(306)**	**(1,400)**
Ordinary profit (loss)	(797)	110	(290)	(160)	(700)	(390)	(296)	(1,410)
Profit (loss) ATOP	(749)	133	(276)	(149)	(670)	(380)	(430)	(1,390)
Selected B/S items	**FY18/12**	**FY19/12**	**FY20/12**	**FY21/12**			**FY22/12**	**FY23/12**
• Cash and deposits	**1,584**	**1,541**	**2,308**	**1,934**			**2,335**	
Total assets	2,074	1,981	2,738	2,463			2,956	
Total liabilities	774	573	574	428			1,083	
Total net assets	1,300	1,408	2,164	2,035			1,873	
Equity ratio	*60.8%*	*70.3%*	*78.9%*	*81.4%*			*62.8%*	

Source: compiled by SIR from TANSHIN financial statements and IR results briefing. Init CE 22.2.10, rev CE 22.11.18.

4Q Flash

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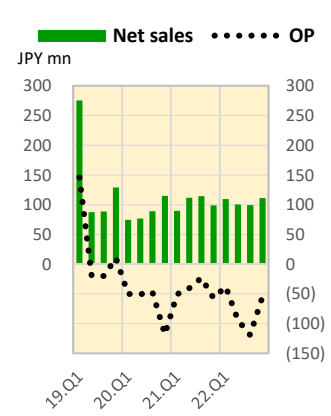

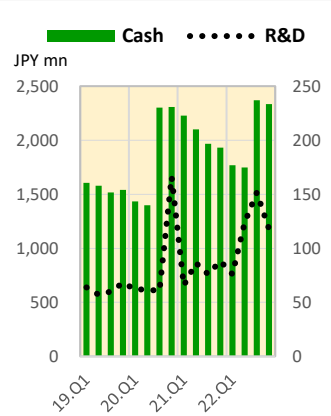

Source: compiled by SIR from TANSHIN financial statements. Cash = cash and deposits on the B/S. Unit: JPY mn.

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