

Snippet roundup: Allergan wins in bipolar depression but BTG loses out in emphysema



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Welcome to your weekly roundup of *EP Vantage's* snippets – short takes on smaller news items.

This week, April 2-6, 2018, we had thoughts on the following: BTG writeoff shows extent of Pneumrx overpayment; Smith & Nephew hires a deal-maker; Allergan makes triple sure with Vraylar label extension; Lilly places marker in diabetes cell therapy.

These snippets were previously published daily [via twitter](#).

BTG writeoff shows extent of Pneumrx overpayment

April 6, 2018

BTG bought Pneumrx in 2014, saying at the time that the \$230m up-front fee was worth it even though it did not expect a return for another four years. Things have not turned out quite like that. Yesterday the company said it was making a £150m (\$210m) writedown on the value of PneumRx Coil, the technology that formed the basis for the acquisition, in a tacit admission that it overpaid for an asset that is either too risky or worth a lot less than it initially believed. The UK group's shares closed down 10%. US approval of the emphysema therapy – the device is a twist of wire designed to improve the tension of inelastic lung tissue, allowing patients to breathe more easily – has been slow in coming, and BTG has made little progress with European reimbursement. An FDA adcom for PneumRx Coil is expected during the summer, and premarket approval might be granted by the end of 2018, but BTG does not expect material revenues from the device for two years at least. Analysts from Deutsche Bank wrote that BTG could still deliver on its double-digit product sales targets even with lower PneumRx Coil sales. Sellside consensus puts these at \$137m in 2022, according to *EvaluateMedTech*. This annual growth rate of 61% means that PneumRx Coil was once expected to be BTG's fastest-growing single product: it has disappointed to say the least.

BTG's interventional devices

Segment (Company)	EvaluateMedTech Device Classification - L3	WW sales (\$m)		
		2017	2022	CAGR
Oncology beads	Embolisation devices	63	74	+3%
Therasphere	Radionuclide microspheres	129	260	+15%
Galil Medical/Cryoablation	Other surgical instruments & accessories	21	39	+14%
Ekosonic	Embolectomy/thrombectomy devices	103	227	+17%
PneumRx Coil	Other respiratory therapeutic devices	13	137	+61%
Other interventional medicine	Unclassified	10	166	+74%
Total interventional medicine		339	903	+22%
Total medtech revenues		346	747	+17%
Total company revenues		812	1,227	+9%

Source: EvaluateMedTech

Smith & Nephew hires a deal-maker

April 4, 2018

The hiring of Alere's former chief executive Namal Nawana to lead Smith & Nephew would appear to suggest that a trade sale is a priority for the UK orthopaedics group. Mr Nawana is a canny deal-maker, having persuaded Abbott to buy Alere for \$5.8bn and then clung onto the deal like grim death as Abbott tried to call it off, owing to Alere missing reporting deadlines, being the subject of two separate US Department of Justice investigations and having to pull one of its technologies from the market amid accuracy concerns. If Mr Nawana can get that deal done – admittedly at the lower price of \$4.6bn – finding a buyer for Smith & Nephew ought to be child's play. Possible acquirers of S&N include Johnson & Johnson, Stryker and Medtronic; if a company does make an offer it might be well advised to make sure the agreement incorporates a breakup provision.



Incoming chief executive Namal Nawana

Allergan makes triple sure with Vraylar label extension

April 4, 2018

Allergan appears to have learnt its lessons when it comes to filing data. Yesterday the speciality group unveiled its third positive phase III trial with cariprazine, trademarked Vraylar, in bipolar depression. The string of good results leaves Allergan firmly on track for a supplementary filing in the second half of the year, further extending the potential patient pool for Vraylar, which is already approved in two indications. The careful clinical steps with bipolar depression are in sharp contrast to the refusal-to-file letter with which Allergan was slapped year for Vraylar in negative symptoms of schizophrenia. Back then the regulator determined that the filing was not "sufficiently complete" to allow a review. This might have been due to Allergan only being able to come up with one positive trial in that indication, when the regulator normally requires at least two for an indication extension. This time around Allergan is taking no chances. And with one of its biggest products, Namenda XR, losing patent protection earlier this year and the future of its dry-eye product Restasis still unclear, the group, which is reportedly considering the sale of its women's health business, will need every extra bit of revenue it can get.

Lilly places marker in diabetes cell therapy

April 4, 2018

Lilly's embrace of a cell therapy approach to treating diabetes is a sign that innovation in peptide therapy and small molecules has come to a crawl. The Indiana-based company handed over \$63m and an undisclosed equity investment to Sigilon Therapeutics for access to a preclinical cell therapy technology aimed at implanting insulin-secreting pancreatic beta cells in patients with type 1 diabetes. Sigilon's technology encapsulates allogeneic cell therapies to help them avoid detection by the immune system. In type 1, where patients begin using insulin supplementation almost immediately upon diagnosis, most of the late stage projects are in the SGLT2 class, which are already big sellers in type 2 diabetes with \$3.1bn in sales in 2017. Innovative approaches in type 1, such as glucokinase stimulants, have not yet earned much attention, similarly to type 2 where GIP agonists and MetAP2 inhibitors are still eyed warily. Still, the cell therapy approach in type 1 diabetes is worth watching - if successful in the clinic and priced well, it would have the potential to reduce or eliminate insulin dependence for a population that has few options to slow the progression of disease.

Selected late stage type 1 diabetes projects

	Product	Company	Mechanism of Action
Filed	Farxiga	AstraZeneca	SGLT2 inhibitor
	Suglat	Astellas Pharma	SGLT2 inhibitor
Phase III	Jardiance	Eli Lilly/Boehringer Ingelheim	SGLT2 inhibitor
	Sotagliflozin	Lexicon Pharmaceuticals/Sanofi	SGLT1 and 2 inhibitor
	Glassia	Shire/Kamada	Alpha-1 proteinase inhibitor
	Dasiglucagon	Zealand Pharma	Glucagon receptor agonist
	LY900014	Eli Lilly	Insulin analogue

Source: EvaluatePharma

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