Evaluate Vantage

November 24, 2017

Snippet roundup: a trial miss for Bayer and Acorda cuts its losses

Elizabeth Cairns

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

This week, November 20 to 24, 2017, we had thoughts on the following: Bayer antibiotic slip could open the door for Insmed; patent ruling endangers Premaitha's UK sales; Rxsight sees its way to market; Livanova loses its rhythm; tozadenant is toast – Acorda abandons Parkinson's drug.

These snippets were previously published daily via twitter.

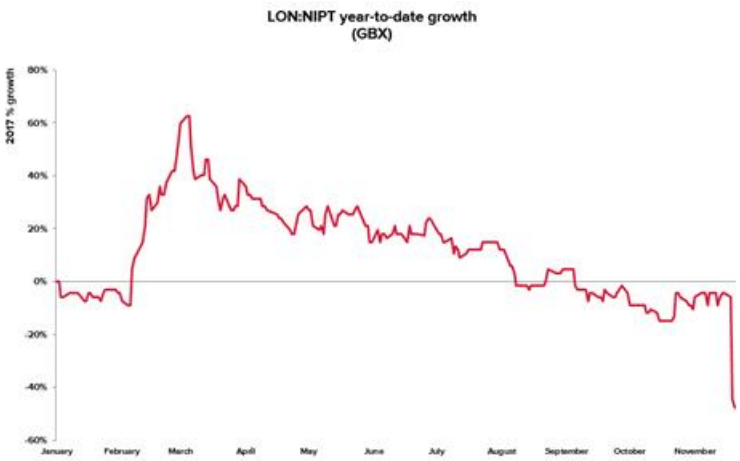
Bayer antibiotic slip could open the door for Insmed

November 24, 2017

The idea seems simple: take a generic antibiotic and reformulate it for use in the lungs, giving it a new lease of life. But reality is not always that easy, as Bayer can attest to with the phase III flop of Amikacin Inhale in Gram-negative pneumonia. The German company and its partner Nektar Therapeutics had hoped that their drug-device combination, using an inhalable formulation of amikacin and a vibrating mesh nebuliser, would improve survival versus intravenous antibiotic therapy alone. It is unclear whether the failure was due to the delivery method, but the trial miss could be good news for Insmed, which posted positive pivotal results with its inhaled amikacin Alis in September, albeit in a different indication, non-tuberculous mycobacterial lung disease. While Insmed does not appear to be trialling Alis in pneumonia at present, it might now see another gap to exploit. However, the market could by stymied by hospitals preparing their own inhaled amikacin from IV formulations. Bayer and Nektar have other priorities – still, a win with Amikacin Inhale would have been a bonus for both companies.

Patent ruling could endanger Premaitha's UK sales

A UK patent judgement against Premaitha Health on Tuesday hit the company hard, initially causing a 35% drop in its shares on Aim. The High Court found that Premaitha's Iona test, which detects foetal DNA in maternal blood to diagnose chromosomal abnormalities such as Down's syndrome, infringes five patents belonging to Illumina. Iona remains on the UK market for now, but sales could be restricted if the court's decision is upheld at an appeal hearing due later this year or in early 2018. The UK market represents approximately 20% of Premaitha's revenues, though the group says this proportion is decreasing. The judgement also found Ariosa Diagnostics, a subsidiary of Roche, to have infringed Illumina's patents, but the finding led to much more severe consequences for the UK firm since Iona is only sold in Europe; Ariosa's Harmony diagnostic is also sold in the US as a lab-developed test and is protected there by US patents. The timing of the judgement is unfortunate: earlier this month a UK screening programme suggested that use of this kind of test boosted the accuracy of detecting Down's syndrome and other conditions.



Rxsight sees its way to market

November 23, 2017

After surgical replacement of their damaged lens with an artificial one cataract patients often still have impaired vision and must wear glasses or undergo another procedure. The US market clearance of an implanted lens that can be tweaked to adjust its power after placement could eliminate this. The lens, developed by Rxsight and named Vision, is made from a material that changes shape when exposed to UV light: beginning around three weeks after the operation, the surgeon uses a proprietary light delivery device to alter the lens to provide the exact visual correction required. The process is conducted over three or four light treatments, each lasting 40 to 150 seconds, spaced over a two or three-week period. The downside is that the patient must wear UV-protective glasses indoors and out from the day of the initial implant to the end of the light treatments. In a 600-patient trial, Vision conferred an average improvement of one additional line down the vision chart after six months without glasses over traditional intraocular lenses. Rxsight, formerly known as Calhoun Vision, has raised more than $140m over the past decade to bring the technology to market, and must hope enough patients see the value in that extra line to allow its backers to recoup their investment.

Rxsight's VC funding, 2007-2017

Date	Round	Investment ($m)	Investor
April 03, 2017	Undisclosed	50.00	Undisclosed
June 04, 2015	Series G	52.00	Longitude Capital, Balance Point Capital Partners, H.I.G. Ventures, RA Capital
March 20, 2014	Series F	12.72	Undisclosed
October 24, 2011	Series E	5.13	Undisclosed
August 27, 2010	Series D	8.54	Undisclosed
May 21, 2007	Series C	15.00	Undisclosed
Total		**143.38**	

Sources: EvaluateMedTech, company website, SEC filings

Livanova loses its rhythm

November 21, 2017

Livanova has been trying to offload its cardiac rhythm management business for a few months, and has now sold the unit, for $190m in cash, to the obvious buyer: its joint venture partner, Microport Scientific. The two companies established Microport Sorin CRM in 2014 – Sorin later merged with Cyberonics to form Livanova – to sell Livanova pacemakers and defibrillators in China, and to develop local CRM devices. The Chinese company held a 51% stake in the joint-venture entity, and has now bought not only the rest of the joint venture but Livanova's entire CRM portfolio. The deal looks cheap since net income from the CRM business came in at $249m in fiscal 2016, but analysts from Berenberg wrote that the sale price was close to their sum-of-the-parts expectation of $194m. They added that the bulk of investors would probably be "pleased to see Livanova exit this business and realise a reasonable price". The deal will allow Livanova to shift capital into its higher-growth businesses – cardiac surgery and neuromodulation – where it has market-leading positions in around 80% of its franchises. The London-based group will take a 5% to 10% hit to its adjusted earnings per share and 20% from its top line this year as a result of the sale.

Livanova at a glance

	WW sales			Market Rank	
	2016	2022	CAGR	2016	2022
Blood transfusion devices	102	97	-1%	5	6
Total blood	**102**	**97**	**-1%**	**11**	**14**
Heart valves	172	190	+2%	5	5
Other cardiac prosthetic devices	13	11	-4%	7	8
Cardiac prosthetic devices	**186**	**201**	**+1%**	**5**	**6**
Pacemakers	213	189	-2%	5	4
Other cardiac rhythm management	125	115	-1%	1	2
Cardiac rhythm management	**337**	**304**	**-2%**	**7**	**7**
Cardiopulmonary bypass devices	541	561	+1%	1	3
Cardiovascular surgical devices	**541**	**561**	**+1%**	**1**	**3**
Total cardiology	**1,064**	**1,066**	**+0%**	**11**	**12**
Neuromodulation devices	476	669	+6%	4	5
Total neurology	**476**	**669**	**+6%**	**6**	**7**
Total sales	***1,642***	***1,831***	***+2%***	***60***	***66***

Source: EvaluateMedTech

Tozadenant is toast – Acorda abandons Parkinson's drug

November 20, 2017

It was hard to see what, if any, future tozadenant had after five fatal sepsis cases were reported last week. So, as foreseen by *EP Vantage*, tozadenant is toast. Acorda Therapeutics announced today that it would discontinue further development of the Parkinson's disease project. This is an eminently sensible move, because even if Acorda had found ways around the safety concerns – and weekly monitoring of patients' blood count apparently would not have been enough – willing payers would have been in short supply. Not flogging the dead horse that is tozadenant should mean more money to spend on Inbrija, which represents the disaster-prone company's last chance to make up for a long list of failures. To get Inbrija across the finish line Acorda also today said it had signed two royalty-sharing agreements with Lundbeck and Healthcare Royalty Partners, raising $53m. This canny royalty play provides a non-dilutive way to launch Inbrija, avoiding the deep discount, and subsequent share price destruction, that would have come with an equity raise. So Acorda rumbles on, but if there are any more problems with Inbrija Acorda will deserve to go the way of tozadenant.

Recent Acorda slip ups

Date	Event
November 2017	Tozadenant abandoned in Parkinson's disease
August 2017	FDA issues refusal to file letter for Inbrija
April 2017	Loss of patent exclusivity for Ampyra
November 2016	Ampyra fails to show improvement in post-stroke walking ability
May 2016	Plumiaz nasal spray abandoned in epilesy

To contact the writers of this story email news@epvantage.com or follow @EPVantage on Twitter