

## Snippet roundup: A biosimilars first and two more medtech deals



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

This week, January 9-13, 2017, we had thoughts on the following: Mylan and Biocon's Herceptin biosimilar first masks true task ahead; Derma is in Integra's sweet spot; Tesaro complete response letter shifts focus to main event; Hill-Rom gets 12% off Mortara; the Illumina mystery takes another twist.

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

### **Mylan and Biocon's Herceptin biosimilar first masks true task ahead**

**January 12, 2017**

Being the first to get the FDA to accept a filing for a biosimilar version of Herceptin might seem like a big deal, but in reality it is just the start of a long and complex path Mylan and Biocon will have to navigate get their drug to US patients. With its easier regulatory pathway, many are expecting Herceptin biosimilars to hit the European market in the second half of 2017. Not so the US, where the regulatory environment remains complex. And things could get more complicated, not only for Mylan and Biocon, but all biosimilars companies. As pointed out by analysts at Bernstein the biosimilars law is part of the Affordable Care Act, which President-elect Donald Trump has vowed to rip up on day one of his presidency. The hope is that he will do away with the law in segments, retaining bits that work. Even if this is the case, despite a September 3 review date analysts at Evercore ISI are not expecting a Herceptin biosimilar to hit the market in the US before 2019. And even then it might not be the end. Despite having gained approval for their biosimilar version of Remicade Celltrion and Pfizer have still not launched. Some believe that this is down to a disagreement over discount levels between PBMs and other distributors. While Mylan and Biocon should get recognition for their pioneering actions any big celebrations are years away.

Status of mAb biosimilars in the US			
	Submitted	Approved	Launched
Herceptin	Mylan/Biocon	x	x
Avastin	Amgen/Allergan	x	x
Humira	x	Amgen	x
Enbrel	x	Novartis	x
Remicade	Samsung Bioepis	x	Pfizer/Celltrion

### **Derma is in Integra's sweet spot**

**January 12, 2017**

After the three megamergers announced in 2014 – Zimmer and Biomet, Steris and Synergy, and Smith & Nephew and Arthrocare – consolidation in the woundcare sector has slowed. Integra Lifesciences' takeout of Derma Sciences, at \$204m, is not in that kind of category, but still speaks to the pressures of competing in this space. Integra has hooked several innovative products including the Medihoney brand and the Amnio membrane technologies, which use placental tissue. Despite the 40% premium Integra paid, Wells Fargo analysts wrote that at roughly twice forward sales the deal was reasonably cheap. According to Integra, Derma will bring in additional revenue of \$65m or so, but the deal will be dilutive to its earnings in the coming year, though accretive to its 2018 Ebitda margin thanks to synergies of around \$20m. Its shares dropped 3% yesterday.

### Derma Sciences

Segment (Company) Tiers - Level 3	EvaluateMedTech Device Classification - L3	WW sales (\$m)		
		2017	2022	CAGR
Algicell AG	Advanced Wound Dressings	5.61	9.08	+10%
Medihoney Wound & Burn Dressings	Advanced Wound Dressings	23.13	37.41	+10%
Bioguard	Advanced Wound Dressings	5.37	8.69	+10%
XTRASORB	Advanced Wound Dressings	4.29	6.93	+10%
TCC-EZ	Advanced Wound Dressings	3.65	5.90	+10%
Other Advanced Wound Care	Advanced Wound Dressings	7.80	12.62	+10%
Traditional Wound Care/ Basic Wound Care	Wound Management (unspecified)	35.23	36.92	+1%
AMNIO franchise	Other Wound Healing Devices	5.16	19.48	+30%
<i>Total MedTech Revenues</i>		<i>90.24</i>	<i>137.05</i>	<i>+9%</i>
<i>Non-MedTech Revenues</i>		<i>15.00</i>	<i>27.50</i>	<i>+13%</i>
<b>Total Company Revenues</b>		<b>105.24</b>	<b>164.55</b>	<b>+9%</b>

Source: EvaluateMedtech

## Tesaro complete response letter shifts focus to main event

January 12, 2017

Ailing sales of Tesaro's treatment for chemotherapy induced nausea and vomiting, Varubi, are likely to ail for a bit longer after yesterday's complete response letter for an IV version of the medicine. Luckily for Tesaro, the issue appears to involve concerns around manufacturing, arguably the best of a bad lot when it comes to FDA knockbacks. Tesaro said it would answer the FDA's questions "expeditiously" and that a first-half launch was still possible. Approval could have provided a much-needed shot in the arm for Varubi sales, which over the past three quarters have only reached \$4.4m for the oral version, leading analysts to downgrade forecasts. But in the grander scheme Varubi is a footnote to Tesaro's main project, the Parp inhibitor niraparib, one of the stars of last year's Esmo conference. The project was recently granted a priority review and could be approved as soon as June 30 in second-line ovarian cancer. If there are any hiccups around this approval then Tesaro investors, who have seen the group's shares fall 5% in a choppy premarket, will have something real to worry about.

### Tesaro 2022 products

Product	2022 WW sales (\$m)	WW Phase (Current)	Patent Expiry
Niraparib	1,794	Filed	Mar-2030
Varubi	382	Marketed	Aug-2028
<b>Total</b>	<b>2,175</b>		

Source: EvaluatePharma

## Hill-Rom gets 12% off Mortara

January 11, 2017

Hill-Rom has got itself a bargain in the January sales. It has acquired Mortara Instrument, which sells electrocardiographs and other cardiovascular monitoring technologies, for \$330m in cash – but reckons the deal will yield a tax benefit that will reduce its effective price to \$290m. The company believes that it can use its global presence to speed the Mortara business's growth, and says Mortara will fit with the Welch Allyn business it acquired for \$2bn in 2015. There will be operational synergies topping \$10m annually, according to Hill-Rom, and the deal, which should close by mid-year, will be "modestly accretive" to adjusted earnings per share for fiscal 2017. Mortara had sales of around \$115m last year, and will presumably slot into Hill-Rom's patient monitoring segment, which brought in around \$810m in 2016.

### Hill-Rom

Segment	WW sales (\$m)			Market share	
	2016	2022	CAGR	2016	2022
Anaesthesia & respiratory	107.2	134.9	3.9%	1.4%	1.3%
General hospital & healthcare supply	1,738.3	2,045.6	2.8%	15.5%	14.3%
Patient monitoring	809.7	1,052.9	4.5%	15.7%	16.1%
<b>Total</b>	<b>2,655.2</b>	<b>3,233.4</b>	<b>3.3%</b>	<b>0.7%</b>	<b>0.6%</b>

Source: EvaluateMedtech

## The Illumina mystery takes another twist

January 10, 2017

One of the most volatile big-cap stocks in medtech is back up. Shares in the sequencing group Illumina rose 17% in the pre-market, boosting its market cap by more than \$2bn, on good quarterly results, a product launch and a couple of deals in the digital health space. At the JP Morgan meeting yesterday the company put fourth-quarter 2016 sales at \$619m, around \$8m above consensus, and set 2017 revenue guidance at \$2.7bn – also better than estimates, though only marginally. Leerink analysts attribute the rise to the launch of the NovaSeq high-throughput sequencing technology, which Illumina says can sequence DNA three times faster and 20% more cheaply than its current tech – despite the analysts also saying that the demand for high-throughput

sequencers across academic and diagnostics labs remained weak into 2017. Perhaps the oncology-focused deals Illumina struck with IBM Watson Health, under which the eponymous supercomputer will be used to improve tumour sequencing and interpret genomics data, and with Philips, under which Illumina's sequencing and Philips's clinical informatics systems will be integrated and co-marketed, were responsible for the share spike. Whatever the reason, Illumina's stock, which lost 25% on October on a profit warning and has fallen badly and recovered four times in the past 18 months, is a byword for resilience.

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