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Daré Bioscience, Inc. (DARE-NASDAQ)

DARE: Adds Late-Stage Bacterial Vaginosis Candidate

We use 5.0x sales and discount revenue at 20%, 15% and 10% reflecting bear, base and bull cases, respectively. Base case puts fair value of DARE at approximately $8.00/share.

Current Price (12/17/18)	$0.69
Valuation	**$8.00**

OUTLOOK

DARE is showing no signs of slowing down as it relates to expanding their women's health focused pipeline and their potential eventual related commercialization opportunities. Their latest addition was announced earlier this month when (on Dec 6th) they revealed that will acquire worldwide rights to a late-stage hydrogel-based treatment for bacterial vaginosis (BV) as well as the underlying proprietary hydrogel drug delivery technology that it is built upon.

Per terms of the agreement, DARE paid $275k upfront and owes another $450k over the next 12 months to the selling parties; Hammock Pharmaceuticals, Inc., TriLogic Pharma LLC and MilanaPharm LLC. DARE is also required to pay potential future milestones based on "clinical, regulatory, commercial launch and sales events", and is also subject to paying royalties on any eventual sales. In return, DARE gets exclusive global rights to MP-101 (clindamycin phosphate 2%) as well as to the hydrogel delivery technology for any vaginal or urological application in humans. Current patents extend through 2028 while patents pending, when effective, would have terms through 2035.

Model updates moves PT to $8.00/share.

SUMMARY DATA

52-Week High	**$3.59**
52-Week Low	**$0.68**
One-Year Return (%)	**-70.14**
Beta	**2.37**
Average Daily Volume (sh)	**269,121**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$9**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**8**
Insider Ownership (%)	**19**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**N/A**
P/E using 2019 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Value**
Industry	**Med-Biomed**

ZACKS ESTIMATES

Revenue
(in '000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2018	0.0 A	0.0 A	0.0 A	0.0 E	0.0 E
2019					
2020					

Earnings Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.27 A	-$1.42 A	-$0.33 A	-$1.48 A	-$3.56 A
2018	-$0.88 A	-$0.32 A	-$0.23 A	-$0.29 E	-$1.60 E
2019					-$0.96 E
2020					-$0.78 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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DARE Acquires Late-Stage Bacterial Vaginosis Candidate

Dare Bioscience is showing no signs of slowing down as it relates to expanding their women's health focused pipeline and their potential eventual related commercialization opportunities. Their latest addition was announced earlier this month when (on Dec 6th) they revealed that they will acquire worldwide rights to a late-stage hydrogel-based treatment for bacterial vaginosis (BV) as well as the underlying proprietary hydrogel drug delivery technology that it is built upon.

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Bacterial Vaginosis, What It Is, How Prevalent and How Is it Treated?

Different kinds of bacteria are present in the vagina and when the bad kind aren't well controlled, bacterial vaginosis can occur. Specifically, lactobacillus, a friendly bacterium typically keeps unfriendly bacteria at bay. But, if that balance is disrupted and lactobacillus levels fall, bad bacteria can proliferate and result in BV. While not all cases of bacterial vaginosis (which is different from a yeast infection) are symptomatic, in those that are, typical symptoms include vaginal discharge, fishy odor and pain when urinating.

As BV is caused by adverse disruption in vaginal bacteria (i.e. microflora), it can increase the risk of acquiring other, serious health problems. This includes HIV, sexually transmitted diseases and, among women that are pregnant, increases the risk of miscarriage, preterm delivery and endometriosis. As such, treatment, particular among pregnant women or those that plan on becoming pregnant, effective treatment is important.

According to results of a large study that surveyed more than 4,600 women aged 14 to 49 years, it is estimated that 29% of American women, or approximately 21M, have bacterial vaginosis at any particular time. The study also found that among those that have the condition, there were no symptoms reported by 84% - which suggests that the U.S. symptomatic population is approximately 3.3M.[1]

First-line treatment of bacterial vaginosis is antibiotics, namely clindamycin, metronidazole or tinidazole – either orally or locally (probiotics are also sometimes used as an adjunct to antibiotics). As the CDC guidelines illustrate (below), these medications must be taken for at least two days and most for five to seven days. History as shown that compliance wanes with longer or otherwise more burdensome dosing regimens – which results in lower effectiveness of the drug regimen. For example, of the estimated 4M women that are treated for BV each year, only roughly one-half are believed to actually finish a five to seven-day treatment course.

Solosec (secnidazole), approved in September 2017 and the newest entry into the antibiotic BV space, is dosed just once and could draw appeal for its lower dosing requirement. DARE's MP-101 is clindamycin engineered in a way to increase exposure to the drug, thereby presumably increasing its effectiveness and/or reducing the dosing burden.

While we discuss effectiveness of antibiotics in more detail below, in general it is estimated that up to 15% of patients are not cured with the first round of treatment and, of those that are, as many as 80% will experience recurrence of the condition. This means that any treatment that can either increase the first-course cure rate, reduce the recurrence rate and/or reduce the treatment burden (without compromise to efficacy), and do so with an acceptable safety and tolerability profile, is likely to experience meaningful adoption.

CDC <u>recommends</u> use of one of the following treatment regimens to address BV;

- Metronidazole 500 mg orally twice a day for 7 days
- Metronidazole gel 0.75%, one full applicator (5 g) intravaginally, once a day for 5 days cream
- Clindamycin cream 2%, one full applicator (5 g) intravaginally at bedtime for 7 days
- Tinidazole 2 g orally once daily for 2 days
- Tinidazole 1 g orally once daily for 5 days

[1] Koumans, Emilia H. et al. The Prevalence of Bacterial Vaginosis in the United States, 2001–2004; Associations With Symptoms, Sexual Behaviors, and Reproductive Health. Sexually Transmitted Diseases: November 2007 - Volume 34 - Issue 11 - p 864-869

- Clindamycin 300 mg orally twice daily for 7 days
- Clindamycin ovules 100 mg intravaginally once at bedtime for 3 days

As it relates to clindamycin ovules, CDC notes that since they can weaken latex and rubber containing birth control products such as condoms and diaphragms, that they recommend against use of these within 72 hours of using clindamycin ovules

Gel Drug Delivery Technology and MP-101…

MP-101 is designed to increase exposure to clindamycin as compared to other topically delivered antibiotics– and, if it can actually do that, it could presumably increase cure rates, decrease recurrence rates and require a less burdensome dosing regimen. Per DARE's press release describing it;

- the proprietary gel drug delivery technology…"The proprietary in-situ gel system, which consists of a combination of a tri block copolymer and a natural polysaccharide, is designed to take advantage of body temperature to undergo solution-to-gel transition, enabling transformation into a bioadhesive gel formulation featuring extended release of the incorporated drug following application at the site of action."
- MP-101…"this proprietary technology is formulated with clindamycin, an antibiotic used to treat certain bacterial infections including BV, and has been engineered to produce a dual release pattern after vaginal application, providing maximum duration of exposure to clindamycin at the site of infection."

Status and Development Plan…

DARE notes that results of an n=30 pilot study demonstrated an 88% cure rate with one administration of MP-101. It is our understanding that this is the totality of the human clinical data supporting the effectiveness of the compound. The data has not been formally published but is summarized in DARE's December investor presentation.

Per DARE's most recent investor presentation, the pilot study showed a better clinical cure rate as compared to Solosec (more detail below), Clindesse (branded clindamycin) and metronidazole. Note, however, that this pilot study is much too small to draw any concrete conclusions relative to efficacy (or safety). But it does suggest potentially compelling competitiveness (if replicated in larger studies).

MP-101 Pilot Study Results

A single dose of DARE-BV1 demonstrated high clinical cure rate compared to other approved products

Efficacy of MP-101 gel for the Treatment of Bacterial Vaginosis			
Product	**Clinical Cure**	**Nugent Cure**	**Therapeutic Cure**
DARE-BV1	88%	67%*	55%*
Solosec® [1]	62%	49%	37%
Clindesse® [2]	42%	64%	56%
Metronidazole vaginal gel, 1.3% [3]	37%	20%	17%

* Based on data from 9 evaluable patients

- 30 subjects; 26 subjects were evaluable
- Test-of-Cure Visit (Day 7 – 14):
  - **88% (n = 23) subjects achieved clinical cure**
  - 5 of 9 subjects had therapeutic cure and 6 of 9 had bacteriologic cures
- Continued Clinical Response Visit (Day 21 – 30):
  - **92% (n = 24) subjects showed continued clinical cure**
  - 6 of 9 subjects had therapeutic cure and 7 of 9 had bacteriologic cures

Source: DARE December 2018 investor presentation

DARE notes that, based on discussions between MilanaPharm and FDA, that they believe that they can move directly to Phase III and that a single study will be sufficient to support an eventual New Drug Application seeking FDA approval. Specifically, as it relates to a Phase III study, DARE anticipates it will encompass 250 women and

begin in 2H'19. Given that clindamycin is generic with a well-established safety profile (spanning over 50 years of use) and, presumably prior discussions with FDA, DARE anticipates being able follow a 505(b)(2) pathway.

Based on our background work, we did not find precedent of another sponsor using the 505(b)(2) pathway for a topical clindamycin-based compound in a bacterial vaginosis indication. Although we did find some for other indications, such as Almirall's Veltin (clindamycin phosphate 1.2% and tretinoin 0.025%) for acne. So, while are far from certain that such a pathway will be deemed appropriate by FDA for MP-101, we do think there are reasonable reasons to believe that it could be.

Based on our due diligence we found…

Appears that Hammock may have had a similar intent…

In January 2017 Hammock Pharmaceuticals announced that they in-licensed exclusive global rights from MilanaPharma/Trilogic Pharma to was the same drug delivery technology that is the subject of DARE's in-licensing agreement. That same PR also notes that Hammock's lead products are (were) metronidazole and clindamycin vaginal gel for the treatment of bacterial vaginosis. While Hammock, at the time, at hoped to initiate a Phase III clinical program in the second half of 2017, that did not happen – and based on our background work, it appears it was likely due to lack of funding. Noteworthy is that their press release also suggests that Hammock was just "officially launched" – which further supports our belief that their lack of development progress was due to insufficient financing.

Effectiveness of current BV therapies is difficult to quantify…

DARE notes that the (n=30) pilot study demonstrated a cure rate of 88% with just one administration of MP-101 and that current BV therapies typically have a success rate of less than 70%. Based on our, admittedly somewhat limited literature review, it appears an 88% cure rate, if confirmed in a larger RCT, could be highly competitive to that of current BV therapies including all of those listed above (as CDC recommended regimens).

Jeane-Pierre Menard complied an excellent review[2] of clinical studies of BV therapies, which included a general comparison of their effectiveness in curing the condition. While somewhat dated (2011), we think it remains wholly relevant given that his review focuses on all of the current CDC recommended treatments as well as therapies that were novel at the time. Among his comments are that it is problematic to compare different BV studies of different BV therapies due to lack of consistent design (including endpoint methodologies) among the various clinical trials.

Nonetheless, his review of results of head-to-head clinical studies does provide some context as to what "competitive" cure rates may constitute. Among some of his findings are (reference his full review for more information);

- **Metronidazole**: cure rates after four weeks of treatment of metronidazole ranged from 58% to 100% vs 5% to 29% for placebo. These results encompass a number of different clinical studies including those that looked at oral and vaginal metronidazole and at various dosing regimens. One or more studies found cure rates as high as 87% following a single 2g oral dose with no difference in duration of effect between the single 2g dose and multiple doses over two or more days. But, another study found a single 2g dose was only associated with a 62% cure rate. Another study found 7-day metronidazole regimen is superior to that of a single-dose regimen. Metronidazole is associated with more side effects than some other BV therapies including metallic taste and (in some cases) candida infection
- **Clindamycin**: one study which evaluated oral versus intravaginal administration found oral at 450mg 3x/day and 2% clindamycin cream 5g once daily for 7 days had similar cure rates. A study comparing clindamycin ovules (for 3 days) with clindamycin cream (for 7 days) found cure rates of 54% and 48%, respectively (not significantly different). A single dose of vaginal clindamycin cream was found to have similar effectiveness and safety to that of a 7-dose regimen of the same. Clindamycin appears to have the most favorable side effect profile of all other standard-of-care BV antibiotics
- **Metronidazole vs clindamycin**: topical clindamycin (2% clindamycin cream 5 g at bedtime for 7 days; ovule 100 mg daily for 3 days) or oral clindamycin (500 mg twice daily for 7 days) appeared to be equivalent to oral (500 mg twice daily for 7 days) or topical metronidazole (0.75% gel 5 g daily for 7 days). Clindamycin appeared to be associated with lower rates of adverse effects such as nausea and metallic taste as compared to oral metronidazole

[2] Jeanne-Pierre Menard. Antibacterial treatment of bacterial vaginosis: current and emerging therapies. International Journal of Women's Health 2011:3 295–305

- **Tinidazole vs metronidazole**: similar effectiveness (~74% tinidazole vs 82% metronidazole) at 14-days as well as similar short-term recurrence rates. Tinidazole has been associated with side effects similar to those of metronidazole including metallic taste, nausea, vomiting, etc.

This is not meant to be an exhaustive list nor necessarily provide any sort of benchmark for what MP-101 would need to meet to be considered competitive as a BV treatment. It should, however, provide some context for not only what it is considered a general level of effectiveness as well as illustrate the futility of trying to make sense out of comparing outcomes of different clinical studies.

So, while the cited 88% cure rate of MP-101 witnessed in the (small pilot) clinical study is encouraging, results of that study are not enough to draw any confident conclusions as to the potential competitiveness of the compound. Eventual results of the proposed n=250 Phase III study could provide much more insight in that regard – although we do not know whether a pivotal study of MP-101 would be designed as non-inferior to an existing antibiotic (such as clindamycin) or to placebo. We may know more in the near future.

Market Potential of MP-101…
Market research firm Global Info Research pegs the total current U.S. BV drug market at about $160M – which supports IMS data from 2016 showing that BV-related clindamycin and metronidazole sales were approximately $30M and $125M, respectively (tinidazole sales were negligible). So, we think we can estimate with reasonable confidence that the U.S. market for BV antibiotics is worth just north of $150M today. And, with ~4M women treated annually for the condition (out of ~21M total that are afflicted at any one time), that means each patient represents, on average, ~$40 of revenue.

Given that longer and more burdensome dosing regimens can result in lower rates of compliance and higher rates of discontinuation, and even less incentive to start therapy altogether, we think a single-dose therapy could have the effect of significantly expanding the overall treated population – perhaps by as much as 50% (i.e. to a total of 6M women).

Solosec appears to be priced at approximately 4x that of clindamycin, which may reflect its convenient single-dose regimen. Lupin's May 2018 press release announcing launch of Solosec mentions that they expect peak sales of their drug to reach $100M - $150M over the next three to four years – which, based on our calculations (including total treated population increasing from 4M to 6M), implies that they believe their more convenient dosing therapy will claim between 7% and 10% market share.

Initial Modeling of MP-101
For initial modeling purposes of MP-101, we think 10% - 15% peak market share is a reasonable assumed starting point. While significantly superior efficacy or easier dosing regimen (which could also benefit the tolerability profile) to topical clindamycin could quickly promote it to first-in-class status, it is too early to estimate with any reasonable degree of confidence how MP-101 will compare to its generic counterpart (or other antibiotics). But, given that we think the presumed due diligence of DARE included more detailed look into development results to-date, the reasonable likelihood that 505(b)(2) is appropriate and the long history of safe use of clindamycin does warrant inclusion of the compound into our model.

The addition of MP-101 to our model, which assumes initial revenue in 2022 and single-digit market share penetration over the first 4 – 5 years after launch, initial double-digit share at year 5 – 6 and peak share of 15%. We assume 60% chance of regulatory success, OUS sales equal to 30% of that of the U.S. and licensing/milestone/royalties payments aggregating to 25% of gross revenue. The addition of MP-101 to our model moves our calculated fair value to $8.00/share. As always, all of our assumptions our subject to updating.

VALUATION WATERFALL

Risk-Adjusted Forecasted Revenue

	$2,020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Ovaprene	$0	$0	$0	$5,291	$22,667	$50,315	$73,489	$85,088	$99,491	$127,987
%of total		-	*0%*	*48%*	*67%*	*68%*	*66%*	*66%*	*66%*	*69%*
PT-101 (VVA)	$0	$0	$0	$1,430	$3,484	$8,840	$16,150	$18,214	$18,487	$18,764
%of total		-	*0%*	*13%*	*10%*	*12%*	*15%*	*14%*	*12%*	*10%*
Topical Sildenafil (FSAD)	$0	$0	$814	$2,203	$4,192	$7,092	$10,941	$14,612	$20,763	$25,591
%of total		-	*45%*	*20%*	*12%*	*10%*	*10%*	*11%*	*14%*	*14%*
MP-101 (BV)	$0	$0	$982	$1,993	$3,569	$8,215	$10,422	$11,196	$12,534	$12,722
%of total		-	*55%*	*18%*	*11%*	*11%*	*9%*	*9%*	*8%*	*7%*
TOTAL Risk-adj Revenue	**$0**	**$0**	**$1,796**	**$10,917**	**$33,911**	**$74,461**	**$111,002**	**$129,109**	**$151,275**	**$185,063**

Risk-Adjusted Market\djusted Market Value

Present Value based on 2029 out-year:	Per-share value	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
20%discount rate	$3.28	$51,530	$64,412	$80,515	$100,644	$125,805	$157,256	$196,570	$245,713	$307,141	$383,926	$479,908	$599,885
15%discount rate	$7.21	$113,327	$133,326	$156,854	$184,534	$217,099	$255,411	$300,483	$353,510	$415,894	$489,287	$575,632	$677,214
10%discount rate	$15.15	$238,254	$264,727	$294,141	$326,823	$363,137	$403,486	$448,317	$498,130	$553,478	$614,976	$683,306	$759,229
Present Value based on 2028 out-year:													
20%discount rate	$4.04	$63,587	$79,484	$99,355	$124,194	$155,242	$194,053	$242,566	$303,207	$379,009	$473,762	$592,202	$740,253
15%discount rate	$8.37	$131,619	$154,845	$182,171	$214,319	$252,140	$296,635	$348,982	$410,568	$483,021	$568,260	$668,541	$786,518
10%discount rate	$16.62	$261,337	$290,374	$322,638	$358,486	$398,318	$442,576	$491,751	$546,390	$607,100	$674,555	$749,506	$832,784
Present Value based on 2027 out-year:													
20%discount rate	$4.13	$64,972	$81,215	$101,519	$126,899	$158,623	$198,279	$247,849	$309,811	$387,264	$484,080	$605,100	
15%discount rate	**$8.05**	$126,574	$148,911	$175,189	$206,105	$242,477	$285,267	$335,608	$394,833	$464,509	$546,481	$642,919	
10%discount rate	$15.10	$237,359	$263,732	$293,035	$325,595	$361,772	$401,969	$446,632	$496,258	$551,398	$612,664	$680,738	
Present Value based on 2026 out-year:													
20%discount rate	$4.41	$69,315	$86,644	$108,305	$135,381	$169,226	$211,533	$264,416	$330,520	$413,150	$516,437		
15%discount rate	**$8.08**	$127,092	$149,519	$175,905	$206,947	$243,467	$286,432	$336,979	$396,446	$466,407	$548,714		
10%discount rate	$14.32	$225,088	$250,098	$277,887	$308,763	$343,070	$381,189	$423,543	$470,603	$522,892	$580,992		
Present Value based on 2025 out-year:													
20%discount rate	$4.74	$74,492	$93,116	$116,394	$145,493	$181,866	$227,333	$284,166	$355,208	$444,010			
15%discount rate	**$8.18**	$128,550	$151,236	$177,924	$209,323	$246,262	$289,720	$340,847	$400,996	$471,760			
10%discount rate	$13.68	$215,023	$238,915	$265,461	$294,956	$327,729	$364,143	$404,604	$449,560	$499,511			
Present Value based on 2024 out-year:													
20%discount rate	$3.97	$62,462	$78,078	$97,597	$121,996	$152,495	$190,619	$238,274	$297,842				
15%discount rate	$6.45	$101,449	$119,352	$140,414	$165,193	$194,344	$228,640	$268,989	$316,457				
10%discount rate	$10.19	$160,264	$178,071	$197,857	$219,841	$244,268	$271,409	$301,565	$335,073				
Present Value based on 2023 out-year:													
20%discount rate	$2.26	$35,559	$44,448	$55,560	$69,450	$86,813	$108,516	$135,645					
15%discount rate	$3.46	$54,356	$63,948	$75,233	$88,510	$104,129	$122,505	$144,123					
10%discount rate	$5.16	$81,098	$90,109	$100,121	$111,246	$123,607	$137,341	$152,601					

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FINANCIAL MODEL

DARE	2017 A	Q1A	Q2A	Q3A	Q4E	2018 E	2019 E	2020 E
Ovaprene U.S. Mkt Assumptions								
Net annual revenue per patient	$200					$300	$300	$300
NuvaRing Avg Annual Patients	1,106,000					1,106,000	1,117,060	1,128,231
NuvaRing Peak US Revenue	$564,000,000					564,000,000	$572,460,000	$581,046,900
U.S. Contracep Product Patient Mkt	23,000,000					$23,000,000	23,000,000	23,460,000
U.S. Contraceptives Mkt Value	$5,500,000,000					$5,500,000,000	5,500,000,000	$5,610,000,000
Ovaprene U.S. Penetration Assumptions								
Penetration of US contraceptives $ value						0.0%	0.0%	0.0%
Penetration of NuvaRing's Peak US patients						0.0%	0.0%	0.0%
Number of Annual U.S. Ovaprene patients						0	0	0
OVAPRENE U.S. REVENUE ($'0	**$0**					**$0**	**$0**	**$0**
OVAPRENE OUS REVENUE						**$0**	**$0**	**$0**
Ovaprene OUS as %of U.S.						85.0%	85.0%	85.0%
TOTAL OVAPRENE REVENUE						**$0**	**$0**	**$0**
yoy growth							-	-
PT-101 U.S. Mkt Assumptions								
Net annual revenue per patient	$2,160					$2,160	$2,182	$2,203
PT-101 Total Patient Market	1,400,000					1,400,000	1,414,000	1,428,140
Osphena Peak US Revenue	$43,000,000					$43,000,000	$43,645,000	$44,299,675
PT-101 Patient Market Value	$3,024,000,000					$3,024,000,000	$3,084,782,400	$3,146,786,526
PT-101 U.S. Penetration Assumptions						0.0%	0.0%	0.0%
Penetration' of Osphena's Peak Revenue						0.0%	0.0%	0.0%
Penetration of US HRP+VVA						0.00%	0.00%	0.00%
U.S. PT-101 REVENUE ($000s)						**$0**	**$0**	**$0**
PT-101 OUS REVENUE						**$0**	**$0**	**$0**
PT-101 OUS as %of U.S.						30.0%	30.0%	30.0%
TOTAL PT-101 REVENUE						**$0**	**$0**	**$0**
yoy growth							-	-
Topical Sildenafil US Mkt Assumptions								
TS Net Annual revenue per patient	$1,560					$1,560	$1,576	$1,591
TS Total US Patient Market	13,000,000					13,000,000	13,195,000	13,392,925
Addyi Peak Revenue	$78,000,000					$78,000,000	$79,170,000	$80,357,550
TS Patient Market Value	$20,280,000,000					$20,280,000,000	$20,790,042,000	$21,312,911,556
TS U.S. Penetration Assumptions								
Penetration' of Addyi's Peak Revenue						0.00%	0.00%	0.00%
Penetration' of FSAD						0.00%	0.00%	0.00%
Total TS REVENUE ($000s)						**$0**	**$0**	**$0**
TS OUS REVENUE						**$0**	**$0**	**$0**
TS OUS as %of U.S.						30.0%	30.0%	30.0%
TOTAL TS REVENUE						**$0**	**$0**	**$0**
yoy growth						-	-	-
MP-101 US Mkt Assumptions								
BV Net Annual revenue per patient	$150					$150	$152	$153
BV Total US Patient Market	6,000,000					6,000,000	6,090,000	6,181,350
BV Antibiotics Peak Revenue	$160,000,000					$160,000,000	$162,400,000	$164,836,000
BV Patient Market Value	$900,000,000					$900,000,000	$922,635,000	$945,839,270
BV U.S. Penetration Assumptions								
Penetration of BV Antibiotics' Peak Revenue						0.00%	0.00%	0.00%
Penetration of BV						0.00%	0.00%	0.00%
Total MP-101 REVENUE ($000s)						**$0**	**$0**	**$0**
MP OUS REVENUE						**$0**	**$0**	**$0**
MP OUS as %of U.S.						30.0%	30.0%	30.0%
TOTAL MP REVENUE						**$0**	**$0**	**$0**
yoy growth						-	-	-
Total Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-	-	-
SG&A	$2,704.9	$1,303.2	$1,157.2	$1,175.0	$1,551.0	$5,186.4	$6,450.0	$6,856.0
%SG&A	-	-	-	-	-	-	-	-
R&D	$984.7	$1,186.7	$2,467.6	$1,446.5	$1,771.0	$6,871.8	$8,224.0	$9,028.0
%R&D	-	-	-	-	-	-	-	-
Impairment of Goodwill	$7,490.9	$5,187.5	$0.0	$0.0	$0.0	$5,187.5	$0.0	$0.0
TOTAL OpEx	**$11,180.5**	**$7,677.4**	**$3,624.8**	**$2,621.6**	**$3,322.0**	**$17,245.8**	**$14,674.0**	**$15,884.0**
%Total OpEx	-	-	-	-	-	-	-	-
Operating Income	($11,180.5)	($7,677.4)	($3,624.8)	($2,621.6)	($3,322.0)	($17,245.8)	($14,674.0)	($15,884.0)
Operating Margin	-	-	-	-	-	-	-	-
Total Other Income (Expense)	($340.7)	($2.0)	$15.1	$28.4	$5.1	$106.6	$28.2	$16.7
Pre-Tax Income	($11,521.2)	($7,679.3)	($3,609.7)	($2,593.2)	($3,316.9)	($17,139.1)	($14,645.8)	($15,867.3)
Tax expense (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($11,521.2)	($7,679.3)	($3,609.7)	($2,593.2)	($3,316.9)	($17,139.1)	($14,645.8)	($15,867.3)
YOY Growth	*1612.7%*	*3049.0%*	*624.5%*	*58.2%*	*-67.4%*	*48.8%*	*-14.5%*	*8.3%*
Net Margin	-	-	-	-	-	-	-	-
EPS (GAAP)	($3.56)	($0.88)	($0.32)	($0.23)	($0.29)	($1.60)	($0.96)	($0.78)
YOY Growth	*342.4%*	*230.0%*	*-42.3%*	*-31.0%*	*-88.2%*	*-55.2%*	*-39.8%*	*-18.6%*
Shares O/S	3,232	8,685	11,422	11,422	11,422	10,738	15,250	20,300

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