Zacks Small-Cap Research

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SANUWAVE Health (SNWV-OTC)

SNWV: FDA Filing Expected in June/July

We have used P/S comp as our valuation methodology – for consistency, we continue to use that. Smith & Nephew currently trades at approximately 2.6x analyst's 2019 forecasted revenue. We have SNWV generating approximately $8M in revenue in 2019 - based on the SNN comp 2019 P/S multiple, this values SNWV at about $0.25/share.

Current Price (05/18/16)	$0.05
Valuation	**$0.25**

OUTLOOK

We would characterize the newly released 24-week data as somewhat 'neutral' – that is, not particularly great, but not particularly terrible. At the very least, it should maintain a chance that dermaPACE eventually receives FDA approval/clearance. SNWV met with FDA in April, following submission of a pre-submission package with the clinical trial results. Expects to file PMA package in June/July for full wound closure label. SNWV will hold investor update call after the filing, at which time we may more know about contents of the package. We think it is more likely than not that FDA's response will not be the final determination. This remains a wait-and-see (hear) situation. We had previously been modeling dermaPACE launch in late 2017 but given that the filing didn't happen in Q1, the mixed 24-week data and introduction of greater ambiguity in terms of what an FDA approval pathway would entail, we recently upwardly adjusted our U.S.-related dermaPACE revenue risk discount. We now model a much more tempered launch occurring towards mid-2018.

SUMMARY DATA

52-Week High	**$0.24**
52-Week Low	**$0.04**
One-Year Return (%)	**-32.90**
Beta	**0.32**
Average Daily Volume (sh)	**193,548**
Shares Outstanding (mil)	**104**
Market Capitalization ($mil)	**$5**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**23**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**2.4**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**N/A**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue
(in 000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	211 A	240 A	144 A	372 A	966 A
2016	269 A	335 E	465 E	525 E	1,594 E
2017					1,997 E
2018					4,613 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.02 A	-$0.02 A	-$0.02 A	-$0.02 A	-$0.08 A
2016	-$0.02 A	-$0.01 E	-$0.01 E	-$0.01 E	-$0.04 E
2017					-$0.04 E
2018					-$0.04 E

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

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Q1 Financial Results, Operational Update:

SANUWAVE announced financial results for the first quarter and provided a business update. Q1 revenue, at $269k, was relatively strong, the highest since Q4 2013 and well ahead of our $185k estimate. It also follows the $372k posted in Q4 2015 which was the highest since at least 2008. And while we had anticipated a pick-up in revenue growth as a result of the company's recently renewed focus on restarting international growth via the cultivation of existing distribution relationships and the initiation of others, we clearly underestimated the early impact.

On the Q4 call management noted that sales through their S. Korean distributor recently picked up and were a major contributor to Q4 revenue. That momentum looks to have carried through to the current year. SNWV indicated that sales in this country should continue to have further upside and are expected to be a focal point of international sales growth in the near term. We model consistent sequential international revenue growth throughout the remainder of 2016 and through the out-years in our model revenue as a result of the company's efforts to reignite overseas sales growth. Management was in Italy during the Q1 earnings call (May 16th) meeting with their distribution partner in that country and had scheduled stops in Belgium, the Middle East, S. Korea, Sweden and Switzerland for the same purpose. The company also expects to bring on additional distribution throughout the year, including in some significant markets in and outside of Europe.

Q1 OpEx was also a highlight. Coming in at just $809k, expenses were at their lowest level in at least the last eight years. And while much of the reduction relates to the lack of meaningful clinical or regulatory costs, particularly as compared to during when the pivotal and supplemental studies were ongoing, some of the decrease also relates to management's concerted efforts to trim expenses where possible.

The net result of relatively strong revenue and low operating expenses (in addition to relatively healthy 73% gross margin) was operating loss of just $691k – which looks to be the best in company history.

SNWV used $1.0M in cash for operating activities, but excluding changes in working capital cash used was just $659k – which is inline with management's guidance on the Q4 call (and reiterated on the Q1 call) of an expected burn rate of $175k - $225k per month. Assuming that level holds throughout the remainder of 2016 and revenue grows from the relatively healthy base in Q1, SNWV could experience further improvement in operating loss. That would, in our opinion, be a meaningfully positive sign as it would indicate that the company may be able to near profitability on international sales alone – a prospect that had not reasonably presented itself in the past.

FDA Filing Expected in June / July…

Relative to the U.S. program – the most significant update since the company's last conference call in early April was that they met with FDA and are now preparing the PMA filing. Management expects to make the submission to FDA in late June or early July and shortly following that will hold an investor update call.

Management refrained from providing specifics regarding their meeting with regulators or much of anything related to the package that they will file – but did note that it is expected to seek a full (i.e. non-limited) label for wound closure. As a reminder, while the combined data (pivotal plus supplemental) did not show statistical significance on 100% wound closure at 12 weeks (primary endpoint), it did at 20 and 24 weeks and there was even more pronounced efficacy in certain sub-groups such as younger and taller patients and those with lower BMI.

While this upcoming filing will not seek an indication specific to any sub-groups, the particularly strong data in those populations does potentially offer options to both FDA and SNWV for a more limited indication in the event the agency deems the submission insufficient to support an unrestricted label for wound closure. In that case, SNWV would likely be required to support the filing with additional data – which likely would include additional clinical studies. In any event, we think it is more likely than not that FDA's response to this filing will not be the final determination and very well may include a request for additional information. We look forward to future updates.

Trial Data Refresher

U.S. dermaPACE Update: Combined data hit 100% closure @ 20, 24 weeks but supplemental trial missed on these measures. Promising sub-group and secondary data…

Additional supplemental clinical study and combined data (i.e. when the pivotal and supplemental data were combined using FDA-agreed Bayesian analysis) were announced in March 2016. As a reminder, 100% wound closure at the 12-week follow-up was the primary endpoint in both the pivotal and supplemental studies. Both studies failed to meet this. A subsequent meeting with FDA revealed that the agency was open to considering the totality of the data to support an efficacy claim in a future regulatory filing. As the pivotal study had shown statistical significance of 100% wound closure at 20 weeks, SNWV analyzed the combined data using that timepoint, as well as at 24 weeks, as a proxy for the primary endpoint.

In October 2015 the company announced that while the supplemental study did not hit statistical significance of 100% wound closure at 20 weeks, the combined data did. We noted that that was a highly promising development as had the combined data not shown statistically superior efficacy of dermaPACE over sham at the 20-week mark, that it was our opinion that the device would have had little to no chance of eventually gaining FDA approval/clearance. And, importantly, safety has not been an issue in either of the studies or when the studies were analyzed together.

On March 24th SNWV announced additional clinical data, through 24 weeks, related to both 100% wound closure as well as secondary endpoints and other potentially relevant results. Particular points of interest in the most recent announcement include;

100% wound closure:

- on combined analysis (i.e. data from both studies analyzed together) dermaPACE showed statistically significant superior efficacy over sham control in 100% wound closure at 24 weeks (in addition to the prior data which showed the same at 20 weeks)
    - 20 weeks: 35.5% dermaPACE vs. 24.4% control, p=0.027
    - 24 weeks: 37.8% dermaPACE vs. 26.2% control, p=0.023
    - In addition, management noted that there was a trend of superior efficacy of dermaPACE in wound closure beginning around week 14
    - 12 weeks: while more dermaPACE patients achieved 100% wound closure at 12 weeks as compared to sham control (22.7% vs. 18.3%), the difference was not statistically significant (p=0.32)
- supplemental study: dermaPACE was not statistically different than that of sham control in 100% wound closure at 20 weeks (p=0.339) or 24 weeks (35.4% vs 26.2%, p=0.254)

Secondary endpoints and other relevant analysis:

- Rate of healing: combined data showed approximately 25% of dermaPACE patients reached wound closure by week 12 (i.e. final follow-up of primary endpoint). The same percentage (25%) in the sham control group did not reach wound closure until day 112 (i.e. end of week 16)
    - combined data showed a statistically significant difference (p=0.0346) through 24 weeks favoring dermaPACE in the time to wound closure
- Wound area reduction: combined data showed statistically significant reduction in wound area favoring dermaPACE. The average wound area reduction in dermaPACE subjects was 1.92cm2 compared to 0.16cm2 in the control group at 24 weeks (p=0.047)
    - combined data showed a statistically significant difference in wound area reduction favoring dermaPACE from the week-six follow up through the end of the study
    - achievement of 50% wound area reduction also favored dermaPACE, although this just missed statistical significance at both 12 and 24 weeks
        - 66.9% of dermaPACE patients achieved at least a 50% decrease in wound size at 12 weeks compared to 60.4% in the control group (p=0.0554)
        - 70.4% of dermaPACE patients achieved at least a 50% decrease in wound size at 24 weeks compared to 61.6% in the control group (p=0.0899)
- Wound expansion: combined data showed statistically significant superior efficacy of dermaPACE compared to control in prevention of wound expansion. dermaPACE demonstrated superior results in the prevention of wound expansion (≥ 10% increase in wound size) over the course of the study at 12 weeks (18.0% versus

31.1%; p=0.005, respectively). While this trend continued through 24 weeks, the difference did not remain statistically significant

- Amputations: at 24 weeks, the limb amputation rate of the target ulcer was 2.3% for dermaPACE versus 3.0% in the control group. While the difference was not statistically different (p=0.745), the trend did favor dermaPACE and, given that amputations are relatively rare, the study would have needed to be much larger to demonstrate statistical difference in amputations
- Recurrence rates: combined data showed that at 24 weeks 92.3% of dermaPACE subjects who demonstrated wound closure did not have a recurrence of DFU versus 88.4% in the control group. Again, while not statistically different (p-value=0.490), the trend in recurrence rate did favor dermaPACE. But, perhaps more important is that this 92.3% non-recurrence rate (which is similar to the 95.5% non-recurrence rate of the pivotal dermaPACE study) compares very favorably to recurrence rates in clinical studies as high as 19% and 40% of Dermagraft and Apligraf, respectively. These are (relatively invasive and costly) skin substitutes used to treat DFU and potential competitors to dermaPACE.

Demographic sub-group analysis: a deeper dive was done to flesh out any differences-of-interest in results based on patient demographics. This could be relevant to design of potential follow-up studies

- **Height:** combined data showed statistically significant superior efficacy of dermaPACE compared to sham control (30.0% vs 14.1%) in 100% wound closure at 12 weeks with patients measuring 70 inches and taller
- **Age, BMI, height, sex:** while the combined data did show statistically superior efficacy of dermaPACE over sham control at 24 weeks, there were sub-populations in which efficacy of dermaPACE was even more pronounced. Patients younger than 65 years, body mass index (BMI) less than 32, height greater than or equal to 70 inches, and male subjects all had success rates statistically significantly higher than the control group ($p = \leq 0.050$).

Safety remains a non-issue: there was not a statistically significant difference in safety between the dermaPACE and control arms in the pivotal or supplemental study or when the data was combined with Bayesian analysis. In the combined data, 73.2% of dermaPACE subjects reported adverse events compared to the control's 68.9% (p=0.338). 55.8% of subjects saw treatment-emergent adverse events versus the control's 51.2% (p=0.444). Differences were not statistically significant.

Our Comments:
We would characterize the newly released 24-week data as somewhat 'neutral' – that is, not particularly great, but not particularly terrible. At the very least, it should maintain a chance that dermaPACE eventually receives FDA approval/clearance. On the less-than-compelling side was that the supplemental study did not show statistical significance difference of 100% wound closure at any time point – 12, 20 or 24 weeks. On the more-encouraging side is that 100% wound closure was met within a sub-group of the supplemental study, 100% wound closure was met at 20 and 24 weeks when the supplemental and pivotal study data was combined, additional sub-groups in the combined data showed even more pronounced efficacy and this combined data, using Bayesian analysis, is what FDA has and continues to state will be what they use for their determination.

As a reminder, FDA has most recently considered 100% wound closure at 12 week follow-up as standard DFU efficacy endpoint with other therapies including Dermagraft and Apligraf. KCI s V.A.C. was approved for the U.S. market when the FDA hurdle was lower and V.A.C. s pivotal trial used 16 and 20-week endpoints it also did not require 100% wound closure. On the other side, in November 2015 Derma Sciences halted the clinical trial for its DFU gel compound, aclerastide. While the DMC overseeing the study reported no safety concerns, lack of efficacy (complete wound closure at 12 weeks) doomed the candidate.

But management has stressed that based on meetings with FDA, the agency will consider the totality of their data – in essence that they will not automatically disqualify dermaPACE because the 12-week 100% wound closure primary endpoint was not met.

SNWV's supplemental clinical study, which enrolled 130 patients, incorporated up to four additional treatments (as compared to the pivotal study) bi-weekly between weeks four and ten. These treatment "boosts" were expected to improve on the efficacy of 100% wound closure as compared to the pivotal study (n=206). Neither study hit this endpoint at the 12-week mark – which was the primary endpoint in both trials. While the pivotal study did show statistically significant superior efficacy of dermaPACE as compared to sham control on 100% wound closure at 20 weeks and 24 weeks, the supplemental study did not.

Given that the supplemental study incorporated treatment "boosts" and the pivotal study did not, the implied lower efficacy in the supplemental study may seem somewhat counterintuitive. However, it may not be that straightforward. One confounding factor, which management pointed out on the Q4 2015 (early April 2016) call, could be the fact that the sham control group in the supplemental study had a more rapid rate of healing as compared to the control cohort in the pivotal study (i.e. – the comparison was more difficult in the supplemental study).

Assuming FDA does consider the totality of the data, there is reason to be hopeful that there is a pathway towards eventual U.S. marketing approval…

- while the supplemental study did not demonstrate an efficacy difference of dermaPACE versus sham control (i.e. standard of care) on the 100% wound closure measure for the entire trial population, it did show a statistically superior difference on this measure in those patients with a BMI of less than 32 (i.e. – less obese patients)
- the pivotal study as well as the combined data showed statistically superior efficacy of dermaPACE compared to sham control at both 20 and 24 weeks.
- combined data showed statistically significant superior efficacy of dermaPACE compared to sham control (30.0% vs 14.1%) in 100% wound closure at 12 weeks with patients measuring 70 inches and taller
- there were sub-populations in which efficacy of dermaPACE was even more pronounced at 24 weeks. Patients younger than 65 years, body mass index (BMI) less than 32, height greater than or equal to 70 inches, and male subjects all had success rates statistically significantly higher than the control group ($p = \leq 0.050$).
- there was also statistically significant differences or at least trends favoring dermaPACE over control in rates of healing, wound area reduction, prevention of wound expansion, amputations and recurrence rates. Recurrence rates of both dermaPACE studies also compare favorably to clinical studies of Dermagraft and Apligraf
- safety has consistently been a non-issue with dermaPACE and is a factor that we think could potentially be the wildcard for SANUWAVE. All other leading DFU therapies (skin substitutes, gels and VAC) are more invasive and susceptible to greater safety risks. As FDA must weigh risk and reward when considering approval of a novel therapy, dermaPACE's relatively low risk profile could work to lower its respective efficacy hurdle
- one-size may not have to fit all with FDA. While 100% wound closure at 12 weeks has been the recent historical standard by which FDA has judged efficacy of DFU therapies, the fact that the agency continues to entertain the possibility of a pathway of approval for dermaPACE may mean they are open to other considerations. SNWV indicated on the Q4 call that their upcoming meeting with FDA will include exploration of what would essentially be alternatives to a label supported with 100% wound closure. This might include indications for use in one or more of the sub-groups where dermaPACE showed particularly strong efficacy such as BMI < 32. Given the strong safety profile of dermaPACE, coupled with efficacy signals in wound area reduction, rate of healing and lower recurrence, potentially there could be an option to seek clearance for use with wounds of certain characteristics. And as dermaPACE is less invasive than other advanced DFU therapies, maybe this opens up the possibility of labelling as more of a first-line treatment and as an adjunct to other less invasive options, including standard of care. Of course the more narrow the label, the more narrow the (indicated) market opportunity (although it could still be used off-label). But the first goal is to just get dermaPACE on the U.S. market, after which there could be an opportunity to broaden its indicated uses.

  While this is all speculation right now, the fact that FDA appears to continue be engaged with SNWV and willing to work with the company towards a potential path forward, is encouraging. SNWV submitted a pre-submission package to FDA with the clinical trial results and met with the agency in April. The company expects to make the PMA filing in late June or early July and following that, will hold an investor update call. So this is a wait-and-see (hear) situation.

Model update:

We had previously been modeling dermaPACE launch in late 2017 but given that the filing didn't happen in Q1, the mixed 24-week data and introduction of greater ambiguity in terms of what an FDA approval pathway would entail, we have upwardly adjusted our U.S.-related dermaPACE revenue risk discount. We now model a much more tempered launch occurring towards mid-2018. We believe that our assumed, yet risk-adjusted, eventual FDA clearance/approval is a reasonable assumption given FDA's continued engagement with SNWV, strong safety profile of dermaPACE, significant efficacy on 100% wound closure in the combined data as well as efficacy in sub-groups (even at 12 weeks) and on secondary measures.

But we also think that the road is now almost certainly more extended – best case scenario from the upcoming meeting seems to be that FDA continues to entertain a pathway forward but requests additional analysis. While we have no idea what to expect in terms of requisite deliverables, history as shown that any back-and-forth process with FDA (not necessarily specific to SNWV) is typically less than efficient and not particularly timely. As such, we think it's very possible an FDA filing does not happen in the current year and are now assuming this is a 2017 event. Our assumptions and model will be updated when more information becomes available.

We have moved our sales haircut (i.e. revenue risk discount) from 50% to 70%. Our haircut represents risk that dermaPACE fails to gain regulatory approval as well as certain operational risks including failure to raise additional capital, slow adoption of dermaPACE upon launch and insufficient sales/marketing capabilities (whether that be in-house or via 3rd party distribution), among others. Additional positive and tangible headway towards approval as well as mitigation of other operational risks would likely warrant a reduction in this risk discount. We have modeled year-2 (year-2 had been assumed to be 2018, we now assume it is 2019) U.S. sales of approximately $15.4 million - which equates to $4.6 million with the risk discount.

We had not previously and still do not incorporate any potential contribution from non-medical applications. This is also subject to updating and is contingent upon further development progress, solidifying proof-of-concept and additional progress towards eventual commercialization – whether organically or via licensing / partnering. It is also possible SNWV looks to just monetize the related IP – which also holds potential promise for revenue, or at least financing upside. To be clear, we think certain of these non-medical applications may have real and, potentially significant value and we continue to remain encouraged by the recent development and validation progress – but we still feel it is too early to assign an estimated value – whether on a related-revenue or related-monetization basis.

Our modeled revenue also consists of OUS sales of ortho/dermaPACE. We think it is reasonable to assume that management's recent efforts to grow ex-U.S. sales via new distribution agreements and entry into new geographically territories can pay dividends in the form of a steepening of the overseas revenue curve. We have OUS sales growing from about $966k in 2015 to approximately $2.6M in 2018.

We have used P/S comp as our valuation methodology – for consistency, we continue to use that. Smith & Nephew currently trades at approximately 2.6x analyst's 2019 forecasted revenue. We have SNWV generating approximately $8M in revenue in 2019 - based on the SNN comp 2019 P/S multiple, this values SNWV at about $0.25/share.

FINANCIAL MODEL

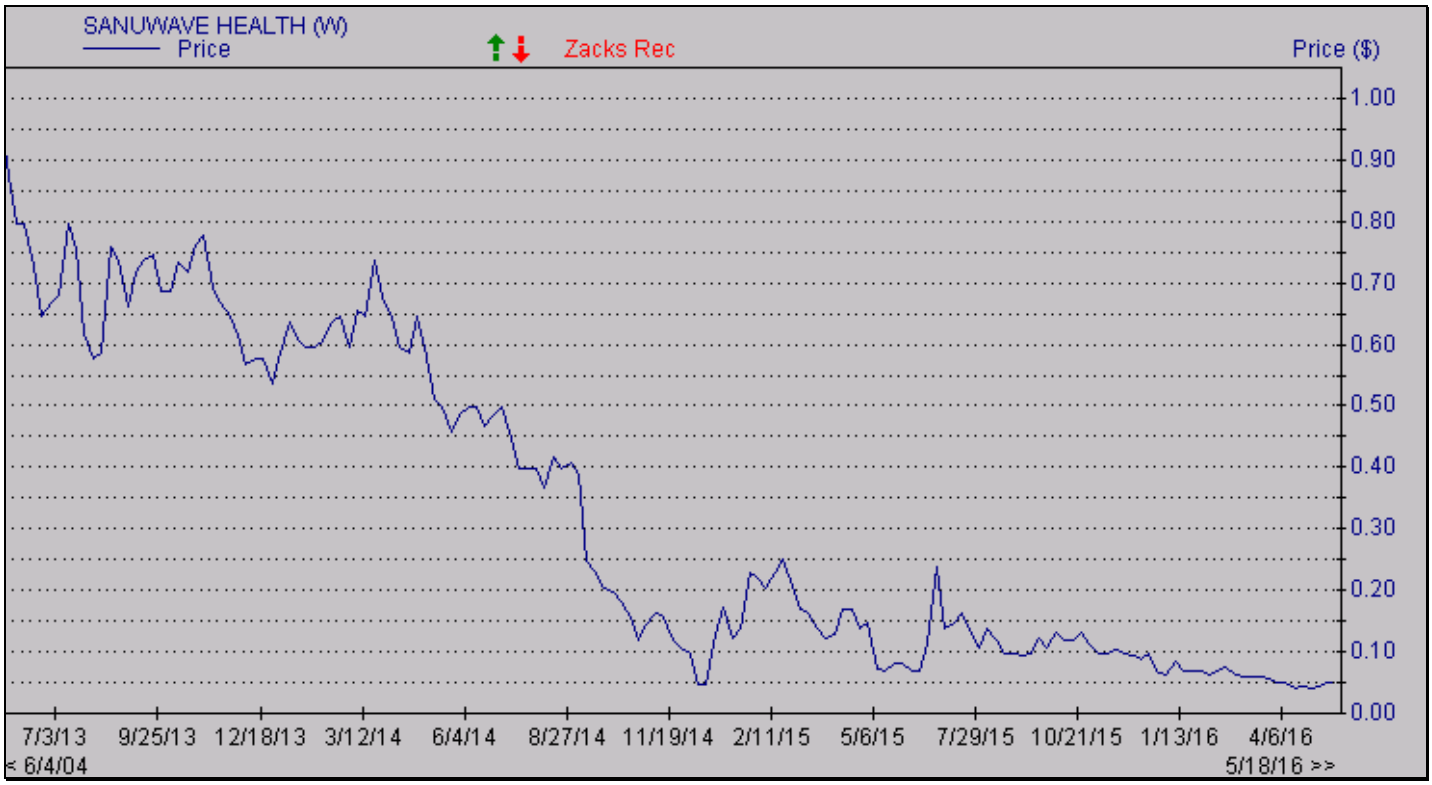
SANUWAVE Health, Inc.

	2015 A	Q1A	Q2E	Q3E	Q4E	2016 E	2017 E	2018 E
Total Revenues	$965.5	$269.3	$335.0	$465.0	$525.0	$1,594.3	$1,997.0	$4,613.0
YOY Growth	*13.9%*	*28.0%*	*39.6%*	*223.8%*	*41.3%*	*65.1%*	*25.3%*	*131.0%*
Cost of Revenues	$285.0	$73.2	$100.5	$139.5	$157.5	$470.7	$567.0	$2,092.8
Gross Income	$680.5	$196.1	$234.5	$325.5	$367.5	$1,123.6	$1,430.1	$2,520.2
Gross Margin	*70.5%*	*72.8%*	*70.0%*	*70.0%*	*70.0%*	*70.5%*	*71.6%*	*54.6%*
R&D	$2,172.9	$310.0	$488.0	$415.0	$586.0	$1,799.0	$2,344.0	$2,218.0
% R&D	*225.0%*	*115.1%*	*145.7%*	*89.2%*	*111.6%*	*112.8%*	*117.4%*	*48.1%*
SG&A	$2,735.1	$499.1	$628.0	$721.0	$688.0	$2,536.1	$2,696.0	$3,326.0
% G&A	*283.3%*	*185.3%*	*187.5%*	*155.1%*	*131.0%*	*159.1%*	*135.0%*	*72.1%*
Depreciation	$3.6	$0.8	$0.9	$0.9	$0.9	$3.5	$40.0	$75.0
Amortization	$306.7	$76.7	$76.7	$76.7	$76.7	$306.8	$55.0	$40.0
Write down of assets	($100.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($4,437.8)	($690.5)	($959.1)	($888.1)	($984.1)	($3,521.8)	($3,704.9)	($3,138.8)
Operating Margin	*-459.6%*	*-256.4%*	*-286.3%*	*-191.0%*	*-187.4%*	*-220.9%*	*-185.5%*	*-68.0%*
Total Other Expense	($372.5)	($1,034.1)	($162.0)	($164.0)	($168.0)	($1,528.1)	($1,260.0)	($1,500.0)
Pre-Tax Income	($4,810.2)	($1,724.6)	($1,121.1)	($1,052.1)	($1,152.1)	($4,252.2)	($4,964.9)	($4,638.8)
Taxes	$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	($4,810.2)	($1,721.6)	($1,121.1)	($1,052.1)	($1,152.1)	($4,252.2)	($4,964.9)	($4,638.8)
YOY Growth	*-19.7%*	*46.9%*	*-26.4%*	*-6.6%*	*14.9%*	*-11.6%*	*16.8%*	*-6.6%*
Net Margin	*-498.2%*	*-639.2%*	*-334.7%*	*-226.3%*	*-219.4%*	*-266.7%*	*-248.6%*	*-100.6%*
EPS (continuing ops)	($0.08)	($0.02)	($0.01)	($0.01)	($0.01)	($0.04)	($0.04)	($0.03)
Diluted Shares O/S	63,025	75,220	105,000	115,000	119,500	103,680	134,000	145,000

Brian Marckx, CFA

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