Zacks Small-Cap Research

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SANUWAVE Health (SNWV-OTC)

SNWV: Management Guiding For FDA Response in January

We have used P/S comp as our valuation methodology – for consistency, we continue to use that. Smith & Nephew currently trades at approximately 2.8x analyst's 2019 forecasted revenue. We have SNWV generating approximately $8.6M in revenue in 2019 - based on the SNN comp 2019 P/S multiple, this values SNWV at about $0.25/share.

Current Price (11/16/16)	$0.18
Valuation	**$0.25**

OUTLOOK

Clearly SNWV decided to consider alternative options and, apparently after additional consultation with MCRA, abandoned the PMA route in favor of the de novo pathway. On August 11th they announced that they submitted a de novo filing to FDA requesting that dermaPACE be classified as a Class II device. SNWV expects a response from the agency in January 2017 and anticipates that FDA with come back with additional questions. We think the de novo pathway makes sense given dermaPACE's strong safety profile and the fact that FDA had previously communicated to SNWV that they will consider the totality of the efficacy data. As we have outlined in our discussion of the combined studies' results, there is an obvious efficacy signal. Another point in dermaPACE's favor, which relates to safety and lack of adverse events, is the non-invasive nature of the device – which would provide an alternative to other relatively invasive DFU therapies including negative pressure and skin substitutes.

SUMMARY DATA

52-Week High	**$0.20**
52-Week Low	**$0.03**
One-Year Return (%)	**62.34**
Beta	**0.59**
Average Daily Volume (sh)	**402,602**
Shares Outstanding (mil)	**137**
Market Capitalization ($mil)	**$24**
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 (%)	**6.6**
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	203 A	256 A	425 E	1,153 E
2017					2,258 E
2018					4,839 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 A	-$0.01 A	-$0.01 E	-$0.05 E
2017					-$0.03 E
2018					-$0.02 E

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

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Q3 Results, Operational Update: *Awaiting Pick Up in International Orders, FDA Response…*

SANUWAVE announced third quarter financial results and provided a brief business update. Revenue trailed our expectations for the second straight quarter which may be the result of an order backlog that has yet to be shipped and booked as revenue. However, based on management's comments on the call, we would expect to see a meaningful pick up in revenue in Q4.

Revenue in Q3 came in at $256k. While this represents yoy and sequential growth of 78% (from $144k in Q3 2015) and 26% (from $203k from Q2 2016), it was about 21% less than our $326k estimate. Nonetheless, the international order book does appear to be picking up – SNWV booked sales of 15 devices through the first nine months of 2016 compared to just eight in the 2015 comparable period. In addition, management noted that Q4 is shaping up to be a potential record quarter, indicating that sales in October and November have been particularly strong and December may be even better.

The uptick in international orders appears to be the fruits of SNWV's recently implemented higher-touch strategy with their third-party distributors. As a reminder, the company recently adopted a more interactive role with their distribution partners in order to better understand and respond to the dynamics and intricacies of each of their OUS markets with the ultimate goal of growing international revenue. In May management visited their distribution partners in Asia, the Middle East and several countries in Europe and came away with a better understanding of how to meet the needs of their distributors. Included in the take-aways was certain distributor contract modifications and lowering pricing, the latter facilitated by updates to their supplier arrangements.

SUNWAVE is exhibiting at the MEDICA conference (November 14 – 17) in Germany and noted on the Q3 call that they are sharing a booth with Ortho Medico, their distribution partner for the Benelux region. This may offer the opportunity to score additional distribution relationships as well as product orders. Management noted that they expect to provide another update on the international order book in early December.

Q3 OpEx was $912k, slightly better than our $1.1M estimate as well as the $1.2M quarterly average in 2015. SNWV continues to have an eye on expense control and has recently implemented additional cost-saving initiatives.

Cash…
Cash used in operating activities was $978k ($881k ex-changes in working capital) and $2.7M ($2.5M ex-changes in working capital) in the three and nine months ending September 30. Cash balance was approximately $504k at Q3 quarter end. SNWV expects monthly cash burn in the remainder of 2016 to average $175k - $225k. We continue to expect the company to look to raise additional cash via the sale of equity or debt or potentially through a partnering arrangement.

FDA Pathway Update…
Relative to the topic of pursuit of FDA clearance of dermaPACE, the only update on the Q3 call was that management now expects to hear back from FDA in January 2017. As a reminder, SNWV filed their de novo application on July 23, 2016 requesting that dermaPACE be classified as a Class II device. As we noted in our update following SNWV's announced de novo filing, as it is not uncommon that FDA's response to de novo filings happens later than their intended goal of 120 days (and can be as long as 400 days), it is possible that the agency's eventual response to SNWV's application will not happen within management's current expectations (i.e. January 2017).

De Novo Refresher

Pursuing De Novo U.S. Regulatory Pathway, Filing Made in July…
On the Q1 call in May management noted that, following their meeting with FDA, that they were in the process of putting together a PMA filing and at that time were anticipating the submission would be made in June or July. Clearly SNWV decided to consider alternative options and, apparently after additional consultation with MCRA, abandoned the PMA route in favor of the de novo pathway. On August 11th they announced that they submitted a de novo filing to FDA (on July 23rd) requesting that dermaPACE be classified as a Class II device. SNWV had noted previously that they were expecting a response from the agency in Q4 of this year but on the Q3 call (on

November 10th) mentioned that they now expect to hear back from FDA in January 2017. SWNV expects that FDA's response, when it does come, will be that they will come back with additional questions.

Our Comments:

De Novo primer: FDA created the de novo pathway in an effort to help streamline approval of novel, low-to-moderate risk medical devices. Prior to de novo the only route for new devices and for which there was not an acceptable predicate, regardless of their risk profile, was the relatively long, arduous and costly PMA process. In other words, novel, low risk devices were, by default, considered Class III, or high risk, medical devices if a similar device had not already been approved by FDA (i.e. lack of predicate excluded 510(k) route).

The 510(k) de novo pathway was created as part of the FDA Modernization Act of 1997 which was meant to streamline the review and approval process for novel, low-risk devices but was so cumbersome (and nonsensically requires the petitioner to first file a 510(k) then for FDA to respond with a 'Not Substantially Equivalent" (i.e. no predicate) letter before it can be refiled as a straight de novo) and time consuming that it was hardly ever used.

The FDA Safety and Innovation Act of 2012 brought a significant change by creating the direct de novo pathway which does not require an initial 510(k) filing. Instead an applicant can directly apply for their device to be considered a Class I or Class II device (with general or general and special controls).

Why SNWV's pivot from PMA to de novo? FDA has some discretion in the criteria and information that they use and how they apply that in determining whether a particular device should be cleared for sale. While this creates some ambiguity in terms of their decision-making process, there is no question that an acceptable benefit-risk profile is of paramount importance. The following document sheds some light on how FDA applies the risk-benefit tradeoff for the PMA pathway and for the de novo pathway.

Per FDA's, "Guidance for Industry and Food and Drug Administration Staff - Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approvals and De Novo Classifications",

> *FDA determines whether PMA applications provide a "reasonable assurance of safety and effectiveness" by "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," among other relevant factors. To aid in this process, PMA applicants submit valid scientific evidence, including one or more clinical investigations where appropriate, which FDA reviews to determine whether "the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device." FDA staff review the data submitted as part of the PMA application and determine – based on a number of factors – if the data support the claims made by the sponsor concerning clinically significant results from the device, i.e., intended use and indications for use, and if the data analysis demonstrates that the probable benefits of the device outweigh its probable risks. A balanced consideration of probable benefits and probable risks is an essential part of FDA's determination that there are reasonable assurances of safety and effectiveness.*

Regarding the de novo pathway it goes on to say,

> *Because devices classified under this pathway (de novo devices) are low to moderate risk devices, they may not need to confer as substantial a benefit to patients in order to have a favorable benefit-risk profile. Devices granted marketing authority under de novo petitions should be sufficiently understood to explain all the risks and benefits of the device such that all risks can be appropriately mitigated through the application of general and/or special controls to provide reasonable assurance of safety and effectiveness.*

If the primary endpoint (statistically superior difference in 100% wound closure at 12 weeks) had been met using the combined (pivotal plus supplemental clinical trials) study data, SNWV would have filed a PMA application. But the primary endpoint was not met. While the clinical data shows an efficacy signal, including significance on 100% wound closure at 20 weeks and, with certain sub-groups (such as high BMI patients), at 12 weeks, we think SNWV concluded (based on advice from MCRA, and potentially from feedback from FDA) that the benefit (i.e. efficacy), as interpreted by FDA under the PMA pathway, was not strong enough to support PMA approval. Or at least, not strong enough for approval without first going through a panel review – a process which would be drawn out and which could still result in a not approvable response.

By pursuing the de novo pathway, SNWV shifts more of the emphasis to the strong safety profile of dermaPACE, essentially lowering the approval hurdle given that, per FDA's guidance above, Class II devices "may not need to confer as substantial a benefit to patients in order to have a favorable benefit-risk profile".

As a reminder safety has been 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.

We think the de novo pathway makes sense given dermaPACE's strong safety profile and the fact that FDA had previously communicated to SNWV that they will consider the totality of the efficacy data. As we have outlined in our discussion of the combined studies' results, there is an obvious efficacy signal. Another point in dermaPACE's favor, which relates to safety and lack of adverse events, is the non-invasive nature of the device – which would provide an alternative to other relatively invasive DFU therapies including negative pressure and skin substitutes.

Other considerations of de novo pathway:

- Review Time: For PMA's FDA's stated goal is to review and make an approval decision within 180 days. For direct de novo applications their stated goal is to make a determination within 120 days. In reality, however, FDA's turnaround time for both pathways is typically much longer than their cited respective timeline goals. PMA applications over the last few years have, on average, taken 15 – 18 months for the FDA to make a decision. And while one of the potential benefits that FDA has cited for the creation of the de novo pathway was reduced review and approval times, according to a study[1] by Hogan Lovells U.S. LLP, average review time for de novo applications in 2014 and 2015 was almost 400 days – while better than average PMA review time, this suggests SNWV may not hear a final decision until well into 2017.

- Competitive considerations: assuming dermaPACE is cleared for sale as a Class II device, it potentially opens the door for competitors to cite it as a predicate device under a 501(k) clearance pathway. However, in reality it may not be that straightforward given the proprietary nature of SNWV's technology, the relative robustness of the randomized clinical trial design and supporting clinical data (notwithstanding the missed primary endpoint) and the special controls (required for a Class II submission) which may provide enough differentiation to thwart any competitors' attempts to claim "substantial equivalence" to dermaPACE. In addition, if SNWV were to successfully expand the label (for example to include other types of chronic wounds), precedent has suggested that FDA may disallow the 510(k) pathway for any competitors (that were successful in citing dermaPACE as a predicate for chronic DFU) seeking the same indication to follow de novo.

- Wasn't an option until 2012: SNWV's pivotal dermaPACE study commenced in 2007 and the third and final module of the PMA filing was made in July 2011. The direct de novo pathway was not an option until July 2012. It's possible that SNWV would have initially chosen the direct de novo route had it been available.

- Switching from PMA to de novo: given the uniqueness of the situation, we do not know if the late-hour switch from PMA to de novo presents the potential for any distinct administrative or regulatory issues with FDA. We assume, however, that MCRA has already addressed anything that may relate to this and has enough comfort of the viability of switching to the de novo pathway

- Lower regulatory burden, cost: the de novo route may provide some relief to the regulatory burden as compared to PMA. While panel review was a real possibility with PMA, there is less likelihood that FDA will convene a panel with de novo. De novo submissions do not require the applicant to pay a user fee and typically will not require post-marketing studies (although the latter can be on a case-by-case basis). And, perhaps, most significant as it relates to regulatory burden is that if SNWV seeks in the future to expand the dermaPACE label, de novo clearance is much more streamlined than if PMA was pursued

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…

[1] http://www.meddeviceonline.com/doc/the-de-novo-classification-process-a-work-in-progress-0001

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.

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. 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. By pursuing the de novo pathway, SNWV shifts more of the emphasis to the strong safety profile of dermaPACE, essentially lowering the approval hurdle given that, per FDA's guidance, Class II devices "may not need to confer as substantial a benefit to patients in order to have a favorable benefit-risk profile"
- 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. Given the strong safety profile of dermaPACE and less invasive nature as compared to other DFU therapies, coupled with efficacy signals in wound area reduction, rate of healing and lower recurrence, we think the de novo pathway makes sense.

Model update:

Our model had previously assumed U.S. launch would happen towards mid-2018, which assumed SNWV followed the PMA pathway. While FDA's target turn-around for a de novo decision is 120 days, history suggests it could be much longer (although still shorter than PMA). As such we assume dermaPACE receives FDA clearance in Q3 2017 and launches in the U.S. late that same year. And while we think the de novo pathway makes sense based on the reasons we cited above, given the ambiguity in terms of FDA's decision-making process along with other unknowns including anything that may be unique to the switch from PMA to de novo, we are maintaining a high (i.e. 70% sales haircut) revenue discount.

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), on secondary measures and less invasive nature of dermaPACE compared to other DFU therapies.

Our 70% 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 dermPACE launching in the U.S. in late 2017. We model 2019 (the second full year that dermaPACE is in U.S. market) U.S. revenue of $16.8 – which equates to $5.0M 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 2.8x analyst's 2019 forecasted revenue. We have SNWV generating approximately $8.6M 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	Q2A	Q3A	Q4E	2016 E	2017 E	2018 E
Total Revenues	$965.5	$269.3	$203.4	$255.7	$425.0	$1,153.4	$2,258.0	$4,839.0
YOY Growth	*13.9%*	*28.0%*	*-15.2%*	*78.0%*	*14.4%*	*19.5%*	*95.8%*	*114.3%*
Cost of Revenues	$285.0	$73.2	$78.0	$98.7	$127.5	$377.3	$641.1	$2,134.8
Gross Income	$680.5	$196.1	$125.4	$157.0	$297.5	$776.0	$1,616.9	$2,704.2
Gross Margin	*70.5%*	*72.8%*	*61.7%*	*61.4%*	*65.0%*	*67.3%*	*71.6%*	*55.9%*
R&D	$2,172.9	$310.0	$476.2	$266.5	$328.0	$1,380.6	$2,344.0	$2,218.0
% R&D	*225.0%*	*115.1%*	*234.1%*	*104.2%*	*77.2%*	*119.7%*	*103.8%*	*45.8%*
SG&A	$2,735.1	$499.1	$589.9	$645.9	$608.0	$2,342.9	$3,048.3	$3,488.9
% G&A	*283.3%*	*185.3%*	*290.0%*	*252.6%*	*143.1%*	*203.1%*	*135.0%*	*72.1%*
Depreciation	$3.6	$0.8	$0.8	$1.6	$0.9	$4.1	$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)	($1,018.2)	($833.6)	($716.1)	($3,258.3)	($3,870.4)	($3,117.7)
Operating Margin	*-459.6%*	*-256.4%*	*-500.6%*	*-326.1%*	*-168.5%*	*-282.5%*	*-171.4%*	*-64.4%*
Total Other Expense	($372.5)	($1,034.1)	($104.0)	($306.2)	($210.0)	($1,654.3)	($1,260.0)	($1,275.0)
Pre-Tax Income	($4,810.2)	($1,724.6)	($1,122.1)	($1,139.8)	($926.1)	($4,099.6)	($5,130.4)	($4,392.7)
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	($4,823.7)	($1,721.6)	($1,127.8)	($1,142.1)	($926.1)	($4,917.6)	($5,130.4)	($4,392.7)
YOY Growth	*-19.5%*	*46.9%*	*-25.9%*	*1.4%*	*-7.6%*	*1.9%*	*4.3%*	*-14.4%*
Net Margin	*-499.6%*	*-639.2%*	*-554.5%*	*-446.7%*	*-217.9%*	*-426.4%*	*-227.2%*	*-90.8%*
EPS (continuing ops)	($0.08)	($0.02)	($0.01)	($0.01)	($0.01)	($0.05)	($0.03)	($0.02)
Diluted Shares O/S	63,025	75,220	102,646	115,529	141,211	108,651	170,000	195,000

Brian Marckx, CFA

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HISTORICAL ZACKS RECOMMENDATIONS



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