Zacks Small-Cap Research

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Aethlon Medical (AEMD-NASDAQ)

AEMD: FDA Discussions Regarding U.S. Pathway

AEMD continues to make substantive positive progress on several fronts. Using sum-of-the-parts valuation and based on current development progress in each respective category we place value of $90M for Hemopurifier in virus, pathogen, bioterror and cancer applications and combined value of ESI and ELLSA technology of $30M. Total company value equates to ~$120M or $15/share

Current Price (02/14/17)	$3.78
Valuation	**$15.00**

OUTLOOK

While the feasibility study has drawn out longer than expected, the lack of safety issues is highly encouraging given that 'success' in this safety study is a gating factor towards moving to the next step in the FDA pathway. Any progress which brings Hemopurifier closer to reaching the U.S. market is additional validation of the utility of the device. As such, we eagerly await results (which, along with safety, are expected to include capture data) of this feasibility study. We also look forward to hearing updates from AEMD's ongoing discussions with FDA given that direction from the agency will also influence the company's near-term U.S. strategy. Timing of read-out of the feasibility study could be favorable given the recent and potential additional changes at FDA aimed at streamlining drug and device approvals. Importantly, Aethlon is considering more than one option relative to a pathway towards U.S. commercialization. The TauSome biomarker could similarly make another significant step towards proving its clinical utility. Success in DETECT was a major milestone, in our opinion, but this larger, follow-on study should provide more definitive information relative to its place in the detection of CTE.

SUMMARY DATA

52-Week High	**$9.09**
52-Week Low	**$3.55**
One-Year Return (%)	**-21.07**
Beta	**2.77**
Average Daily Volume (sh)	**22,921**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$29**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**5**
Insider Ownership (%)	**10**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-17.6**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**N/A**
P/E using 2018 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**N/A**
Industry	**Med-Hmo**

ZACKS ESTIMATES

Revenue
(in '000 of $)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2015	0.1 A	0.5 A	0.0 A	0.2 A	0.8 A
2016	0.2 A	0.2 A	0.3 A	0.2 A	0.9 A
2017	0.0 A	0.4 A	0.0 A	0.0 E	0.4 E
2018					0.0 E

Earnings per Share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2015	-$0.80 A	-$0.16 A	-$0.26 A	-$0.13 A	-$1.22 A
2016	-$0.18 A	-$0.16 A	-$0.16 A	-$0.16 A	-$0.66 A
2017	-$0.28 A	-$0.29 A	-$0.15 A	-$0.18 E	-$0.90 E
2018					-$0.83 E

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

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Fiscal Q3 2017 Financials, Operational Update…

Aethlon reported financial results for their fiscal third quarter 2017 (ending December 2016) and provided an operational update. There were no meaningful surprises in the financial results relative to our expectations with the top-line ($0 A vs. $8k E), operating expenses ($1.2M A vs. $1.3M E), net loss ($1.2M A vs. $1.3M E) and EPS (-$0.15 A vs. -$0.16) E) all coming in just about exactly where we had modeled.

Relative to the balance sheet, AEMD exited fiscal Q3 with $628k cash and equivalents. They raised $288k and $578k (net) from the sale of equity (via ATM) and convertible notes, respectively, during the quarter. Subsequent to quarter-end, AEMD raised an additional $256k (net) via the sale of 64k common shares @ $3.98/share average through their ATM program. Aethlon raised ~$810k through the ATM program since the beginning of Q2 and there remains ~$11M still available.

Cash used in operating activities was $788k ($941k ex-changes in working capital) and $2.6M ($2.7M ex-changes in working capital) through the three and nine months ending December 31st.

On the Operational Front…

The **U.S. feasibility study** is nearing completion. In January the company announced that they had identified the 9th (of a total of 10) patient for enrollment. They are now working to enroll the final participant. **Safety appears to be a non-issue** with management noting on the Q3 call (Feb 10th) that no device-related adverse events have been reported – as safety is the gating factor towards moving to follow-on U.S. studies, the update is obviously positive news. And while this is primarily a safety study, an assessment as to how much of the virus was captured is also expected to be included in the results.

Next steps, assuming positive results of this feasibility study, are yet to be determined but could include one or more pathways – the decision-making related to which will likely be shaped by feedback from FDA. As every situation is different when it comes to FDA, we have no solid basis for making any predictions relative to what to expect from the agency. That said, we expect a strong safety profile from the feasibility study along with quantifiable in-vitro (and some human) capture data would play in AEMD's favor given the severity of their current target indications and absence of effective therapies.

We also think recent **changes at FDA aimed at speeding approval of certain medical devices**, particularly those for which there are no alternative therapies, is also a potential positive for AEMD in their quest towards bringing Hemopurifier to the U.S. market. An example is FDA's Expedited Access Pathway which launched in April 2015 and is designed to reduce the approval time and burden of medical devices that address life-threatening diseases and conditions. And more approval-facilitating changes could be forthcoming - **President Trump has indicated a desire to reduce regulatory burdens** related to drug and device approvals.

AEMD has already engaged FDA for feedback of trial designs related to potential pathways to bring Hemopurifier to the U.S. market. Management is currently considering;

- **Highly virulent viruses in which controlled human studies are not feasible**: This could include both bioterror as well as pandemic threats. Category "A" bioterror threats and pandemic viruses would likely fall in these categories. As a reminder, Hemopurifier has shown utility in capturing a variety of viruses and pathogens that could fall into this category including Ebola, Zika, Chikungunya, Dengue virus, H1N1 swine flu, H5N1 bird flu virus, the reconstructed Spanish flu of 1918 virus, West Nile virus and MERS. Some of the validation work for these targets was done in conjunction with government agencies including the U.S. CDC. and the U.S. Army Medical Research Institute for Infectious Diseases.

  This may be an FDA pathway that lends itself to either partial or full funding from additional government grants. As a reminder AEMD recently communicated that one of their primary objectives is to be able to fulfill the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) goal of developing broad-spectrum medical countermeasures (MCM). PHEMCE is an interagency governmental organization comprised of HHS, CDC, NIH, FDA, VA, DoD, DHS and USDA with a goal of coordinat(ing) the development, acquisition, stockpiling, and use of medical products that are needed to effectively respond to a variety of high-consequence public health emergencies, whether naturally occurring or intentional."
- **Targets for which controlled human studies are feasible**: this includes viral pathogens. AEMD is also exploring additional human studies in the capture of tumor-derived exosomes. AEMD is exploring the Expedited Access pathway as well as traditional FDA pathway.

- **21st Century Cures Act: passed by the U.S. Congress in December 2016**. Among the most attractive parts of this as it relates to medical devices is that it created a priority review program for "breakthrough" devices (modeled after breakthrough pathway for drugs) – this is broader than the existing Expedited Access Pathway for devices and relates to devices for life threatening diseases with no FDA-approved alternative. Given that there are no FDA-approved treatments for most viruses, AEMD will seek guidance (once a new FDA Director is appointed) from the FDA on how they may be able to leverage the Cures Act towards a potential U.S. regulatory clearance pathway. President Trump has indicated a desire to streamline drug and device regulatory approvals which we expect will influence his choice for FDA Director. That, along with this Cures Act, could open up additional opportunities for Aethlon.

Meanwhile, AEMD continues on parallel fronts which includes building on the breadth of the utility of Hemopurifier in additional targets. Recently this includes a study which validated the ability of Hemopurifier to capture (in-vitro) Epstein-Barr virus (EBV), Cytomegalovirus (CMV) and Herpes Simplix virus (HSV), all of which have been associated with higher mortality among sepsis patients. This program focuses, at least in part, on the connection between immune suppression and the reactivation of latent viral pathogens (such as EBV, HSV and CMV) and the relation to compromised patient outcomes. Management noted on the Q3 call that they also now have preliminary observations related to the simultaneous capture of all three viruses.

While this program is still in the early stages, in late 2016 Aethlon along with the University of Pittsburgh initiated a study to detect the presence of EBV, CMV and HSV in blood samples of patients in the intensive care unit. The Hemopurifier will then be assessed in the capture of these viral targets. To-date, samples from 15 patients have been collected.

Relative to ESI, Aethlon is looking to build on the success of their findings as part of the DETECT study and expects to initiate the largest study to-date in NFL players in the detection of CTE in living individuals. As a reminder, Aethlon's majority-owned subsidiary Exosome Sciences has collaborated with Boston University's CTE Center for the development of a blood-based diagnostic that would be able to identify CTE in living individuals. Results from DETECT (see below for more details), presented in April 2015, showed that the NFL players had significantly higher levels of TauSome (tau) in their blood/plasma than those of the controls. Tau levels were also correlated to performance on cognition tests, with higher tau levels corresponding to poorer test performance. Investigators concluded that TauSome levels in blood plasma may be an accurate biomarker for CTE.

The goal of AEMD's new study, announced in January 2017 and which is expected to commence in Q2, is to further validate TauSome as an accurate, non-invasive, reliable biomarker for the diagnosis of CTE in living individuals. This and other studies should provide additional data points and provide more insight into the potential future utility of the diagnostic for CTE – and potentially other conditions such as Alzheimer's disease. While the DETECT study included 78 former NFL players (and 16 controls), this new study is expected to enroll up to 200 former NFL players at several U.S. sites – at full enrollment it would be the largest study in NFL players at risk of CTE.

Aethlon conducted an awareness-building campaign leading up the Super Bowl (Feb 5th) in order to facilitate enrollment. Management noted that the campaign, which included more than 35 interviews with the media including the major television networks, was an overwhelming success. Efforts such as this, along with CEO Jim Joyce's personal contacts (Mr. Joyce was himself an NFL player) and AEMD's relationship with the BU's CTE Center should all aid in getting the study off the ground and with patient enrollment efforts.

Success in DETECT was a major milestone, in our opinion, but this larger, follow-on study should provide more definitive information relative TauSome's place in the detection of CTE (as well as potentially its relationship to other diseases such as Alzheimer's) – a goal that has escaped the clinical community so far and one that would be a major breakthrough and likely be instrumental in helping to shape the diagnosis, treatment and monitoring of the disease. As such, we look forward to updates on the progress of both the Hemopurifier and ESI related programs throughout 2017.

CTE Study Refresher…

As a reminder, Aethlon's majority-owned subsidiary Exosome Sciences (ESI) has collaborated with Boston University's CTE Center for the development of a blood-based diagnostic that would be able to identify CTE in living individuals. ESI has used what they learned in how to isolate certain brain-specific biomarkers to evaluate

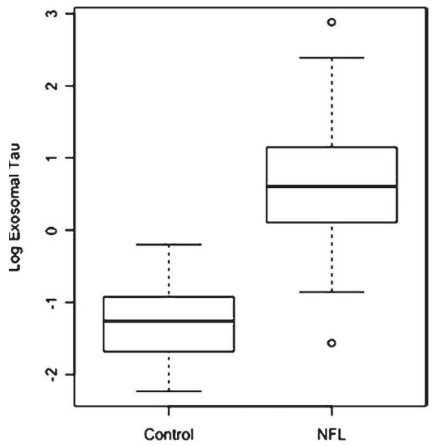
blood/plasma samples collected by participants (former NFL players and a control group) enrolled in BU's DETECT study. The study is the first on CTE funded by the NIH.

In April 2015 investigators presented initial findings of DETECT at the annual Traumatic Brain Injury Conference held in Washington, DC. Results were from 78 former NFL players and 16 controls and showed that the NFL players had significantly higher levels of tausome (tau) in their blood/plasma than those of the controls. Tau levels were also correlated to performance on cognition tests, with higher tau levels corresponding to poorer test performance.

Aethlon submitted a manuscript of the study in 2015, which was published in the online version of the Journal of Alzheimer's Disease in May. Inclusion criteria for the NFL group included age 40-69, a minimum of 12 years of tackle football including a minimum of 2 years in NFL at position associated with extensive head impacts and a self-report of having symptoms associated with CTE including changes in cognition, behavior and mood. Inclusion criteria for control included male age 40-69, minimum of 4 years in non-contact sports including 2 at college level or higher.

The publication provided additional details of the results which included (all charts and graphics[1]);

- Total plasma exosomes did not differ between the NFL and control groups and NFL did have significantly higher ($p<0.0001$) plasma exosomal tau (results in figure below are unadjusted for age)



- Plasma exosome levels were still statistically significantly higher ($p<0.0001$) in the NFL group than in control after adjusting for age and body mass (BMI)

Parameter estimates of ANCOVA for exosomal tau

Predictor	Estimate	Standard Error	*t*-test	*p*-value
Difference of control minus NFL exosomal tau levels	–1.93	0.24	–8.05	<0.0001
Age	0.01	0.01	1.20	0.2351
Body Mass Index	0.01	0.02	0.34	0.7319

- The diagnostic demonstrated 82% sensitivity with 100% specificity, 100% positive predictive value and 53% negative predictive value. In other words, all of the elevated tau results came from NFL players, although not all NFL players showed elevated tau levels

- In the NFL cohort, tau levels were statistically significantly inversely correlated to performance on cognition tests (Wechsler Adult Intelligence Scale Digital Symbol and Neuropsychological Assessment Battery List Learning)

[1] Preliminary Study of Plasma Exosomal Tau as a Potential Biomarker for Chronic Traumatic Encephalopathy. Stern, Robert A. et al. Journal of Alzheimer's Disease, vol. Preprint, no. Preprint, pp. 1-11, 2016

- While exosomal tau was statistically correlated to cognition, it was not correlated to any of the mood or behavioral measures

Relationship between log exosomal tau and measures of cognition, mood, and behavior from mixed effects regression analysis adjusted for age and education as well as for associations of multiple tests per subject and correlations of tests within the same domain for the NFL group only

Domain and Measure	Partial Correlation	Beta Estimate	Standard Error	t-test	p-value
Psychomotor Speed					
Wechsler Adult Intelligence Scale-Revised [78] Digit Symbol Test, Raw Score	–0.33	–3.01	1.16	–2.60	0.0093
Trail Making Test [79] Part A, T-Score	–0.18	–2.03	1.52	–1.33	0.1826
Executive Functioning					
Trail Making Test [79] Part B, T-Score	–0.03	–0.11	2.15	–0.05	0.9589
Wisconsin Card Sorting Test [80] Percent Errors, T-score	–0.09	–0.74	1.28	–0.58	0.5605
Rey-Osterreith Complex Figure –Boston Qualitative Scoring System (BQSS) [81] Organization Score, T-score	0.09	1.69	2.06	0.82	0.4117
Behavior Rating Inventory of Executive Function–Adult Version (BRIEF-A) [82] Metacognition Index, T-score	0.01	0.34	1.75	0.20	0.8434
Learning and Memory					
BQSS [81] Immediate Presence & Accuracy, T-score	–0.14	–1.14	1.32	–0.86	0.3879
BQSS [81] Delayed Presence & Accuracy, T-score	–0.19	–1.74	1.44	–1.21	0.2258
Neuropsychological Assessment Battery (NAB) [83] List Learning Test List A Immediate Recall, T-score	–0.31	–2.84	1.14	–2.50	0.0126
NAB [83] List Learning Test List A Short Delay Recall, T-score	–0.29	–3.41	1.63	–2.09	0.0365
NAB [83] List Learning Test List A Long Delay Recall, T-score	–0.30	–4.35	1.78	–2.44	0.0147
Visuospatial Skills					
NAB [83] Map Reading Test, T-score	0.11	1.38	1.25	1.10	0.2709
Language					
NAB [83] Naming Test, T-Score	–0.12	–1.41	1.46	–0.97	0.3336
Mood					

Key Takeaways:

- ESI's CTE diagnostic demonstrated
    - exosome tau was significantly higher in NFL players than in control
    - exosome tau was significantly correlated to performance on cognition tests. Higher levels of tau correlated to poorer test performance on memory and psychomotor speed tests

- Exosome tau was not correlated to mood or behavior measures
- Highest levels of tau were found only in NFL players although not all NFL players had high levels of tau
- Confirmation that the diagnostic can accurately identify individuals with CTE would require neuropathological examination of the brain

Relative to the lack of association between tau levels and mood/behavior test results, the investigators noted that there is evidence suggesting tau is a better indicator of cognitive function than it is of mood/behavior and that CTE-related cognitive functionality impairments have been reported to be more prevalent in later stage of the disease as compared to mood/behavior changes. In addition, they note "It is possible that the mood and behavioral features

may have multiple potential etiologies, in addition to CTE-associated tau degeneration, whereas the cognitive changes are more consistently due to the tau degeneration."

Relative to the fact that not all NFL players had high levels of tau – the investigators indicated that this was not a surprise as it should be expected that not all NFL players, even those in the study (i.e. – which have at least some symptoms), would have CTE.

While the investigators concluded that these findings suggest exosomal tau in plasma may be an accurate biomarker for CTE, additional research needs to be done. They note some limitations of the study including that;

- confirmation of association between exosome tau and CTE would require a neuropathological exam
- the study did not include markers for where the tau originated so there was not complete confidence that these were all brain-derived exosomes (tau is also present in other areas of the body besides the brain)
- and if these were brain-derived exosomes, the study was also not powered to differentiate between where in the brain they came from (i.e. – neuronal vs, non-neuronal, which may have implications)
- small sample size of the study (particularly control)
- lack of an additional biomarker for CTE

Outlook

The company continues to make substantive positive progress on several fronts including an ongoing ability to raise capital, diligence on cash burn and operating expenses, enrollment of the U.S. feasibility study and commencement of a new CTE study. While the feasibility study has drawn out longer than expected, the lack of safety issues is highly encouraging given that 'success' in this safety study is a gating factor towards moving to the next step in the FDA pathway. And progress, even incremental progress, which brings Hemopurifier closer to reaching the U.S. market is additional validation of the utility of the device. As such, we eagerly await results (which, along with safety, are expected to include capture data) of this feasibility study.

We also look forward to hearing updates from AEMD's ongoing discussions with FDA given that direction from the agency will also influence the company's near-term U.S. strategy. Timing of read-out of the feasibility study could be favorable given the recent and potential additional changes at FDA aimed at streamlining drug and device approvals. And, importantly, Aethlon is considering more than one option relative to a pathway towards U.S. commercialization.

Relative to ESI, the new, larger CTE study should provide more definitive information relative TauSome's place in the detection of CTE (as well as potentially its relationship to other diseases such as Alzheimer's) – a goal that has escaped the clinical community so far and one that would be a major breakthrough and likely be instrumental in helping to shape the diagnosis, treatment and monitoring of the disease. While we do not expect much in the way of near-term performance-related updates, we do look forward to hearing updates on progression of enrollment over the coming months.

Given the near-conclusion of the feasibility study and ongoing conversations with FDA regarding potential U.S. pathways for Hemopurifier, there is potential for some significant near-term operational updates and, by extension, potential for share-price inflection points. Our valuation will continue to consider development progress of both the Hemopurifier and ESI segment.

Using sum-of-the-parts valuation and based on current development progress in each respective category we place value of $90M for Hemopurifier in virus, pathogen, bioterror and cancer applications and combined value of ESI and ELLSA technology of $30M. As such, we value AEMD at approximately $120M or ~$15/share. We will revisit our valuation upon further development progress.

PROJECTED INCOME STATMENT

Aethlon Medical, Inc.

	2014 A	2015 A	Q1 A	Q2 A	Q3 A	Q4 A	2016 A	Q1 A	Q2 A	Q3 A	Q4 E	2017 E	2018 E
Revenue	$1,623.8	$762.4	$192.5	$188.4	$301.0	$204.6	$886.6	$4.6	$387.4	$0.0	$0.0	$392.1	$0.0
YOY Growth	*32.0%*	*-53.0%*	*275.3%*	*-60.7%*	*800.4%*	*3.0%*	*16.3%*	*-97.6%*	*105.7%*	*-100.0%*	*-100.0%*	*-55.8%*	*-100.0%*
Cost of Goods Sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Income	$1,623.8	$762.4	$192.5	$188.4	$301.0	$204.6	$886.6	$4.6	$387.4	$0.0	$0.0	$392.1	$0.0
Gross Margin	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	-	-	*100.0%*	-
SG&A	$3,170.4	$3,727.7	$1,100.5	$1,105.1	$1,237.4	$1,046.5	$4,489.4	$1,018.3	$2,333.3	$1,057.1	$1,144.0	$5,552.6	$4,844.0
%SG&A	*195.2%*	*488.9%*	*571.7%*	*586.7%*	*411.0%*	*511.4%*	*506.4%*	*21969.5%*	*602.2%*	-	-	*1416.2%*	-
R&D	$1,509.0	$1,027.6	$182.0	$207.7	$147.8	$244.5	$782.0	$118.0	$280.9	$178.4	$204.0	$781.3	$1,815.0
%R&D	*92.9%*	*134.8%*	*94.5%*	*110.3%*	*49.1%*	*119.5%*	*88.2%*	*2545.8%*	*72.5%*	-	-	*199.3%*	-
Impairment	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($3,055.6)	($3,992.8)	($1,090.0)	($1,124.4)	($1,084.1)	($1,086.4)	($4,384.8)	($1,131.7)	($2,226.7)	($1,235.5)	($1,348.0)	($5,941.9)	($6,659.0)
Operating Margin	-	-	-	-	-	-	*-494.6%*	-	-	-	-	*-1515.5%*	-
Loss on extinguishment of debt	$40.3	$2,754.0	$0.0	$0.0	$0.0	$0.0	$0.0	$616.9	$0.0	($58.7)	$0.0	$558.2	$0.0
(Gain)/loss on derivative liability	$8,547.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Interest (income), net	$1,287.2	$452.3	$126.7	$127.2	$148.9	$171.0	$573.8	$42.2	$36.6	$36.6	$94.0	$209.3	$418.0
Other expense	$508.6	($219.6)	$0.0	$0.0	$0.0	$0.0	$0.0	$345.8	$0.0	$0.0	$0.0	$345.8	$0.0
Pre-Tax Income	($13,438.6)	($6,979.5)	($1,216.7)	($1,251.6)	($1,233.0)	($1,257.3)	($4,958.6)	($2,136.5)	($2,263.3)	($1,213.4)	($1,442.0)	($7,055.2)	($7,077.0)
Taxes (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$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%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($13,356.9)	($6,797.2)	($1,183.0)	($1,224.6)	($1,217.2)	($1,247.5)	($4,872.4)	($2,128.8)	($2,255.6)	($1,205.7)	($1,442.0)	($7,032.1)	($7,077.0)
Net Margin	-	*-891.5%*	-	-	-	-	*-549.6%*	-	-	-	-	*-1793.6%*	*#DIV/0!*
EPS	($3.44)	($1.22)	($0.18)	($0.16)	($0.16)	($0.16)	($0.66)	($0.28)	($0.29)	($0.15)	($0.18)	($0.90)	($0.83)
YOY Growth	*110.0%*	*-64.7%*	*-78.1%*				*-45.8%*	-	-	-	-	*36.2%*	*196.4%*
Diluted Shares O/S	3,881	5,594	6,720	7,610	7,617	7,627	7,394	7,622	7,757	7,927	8,035	7,835	8,550

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