Zacks Small-Cap Research

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Medgenics Inc (MDGN-AMEX)

MDGN: Efficacy Through 10 Months, Add'l Studies Commencing

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	06/08/2014
Current Price (04/21/15)	$9.12
Target Price	**$12.00**

OUTLOOK

New management team brought on in late 2013 with goal of accelerating development of flagship Biopump technology for orphan and rare diseases. Biopump, a novel ex-vivo gene therapy which uses the patient's own skin to produce and deliver proteins/peptides, has significant advantages over traditional gene therapies. Initial clinical studies demonstrated efficacy and excellent safety. With proof-of-concept accomplished, Biopump is being further validated in a recently initiated phase I/II study - preliminary data from which has been very promising. Rare/orphan disease markets are particularly attractive due to certain incentives and inherent economics. Clinical development may also be accomplished faster, cheaper and with lower risk.

SUMMARY DATA

52-Week High	**$9.63**
52-Week Low	**$3.68**
One-Year Return (%)	**40.00**
Beta	**0.16**
Average Daily Volume (sh)	**83,594**
Shares Outstanding (mil)	**25**
Market Capitalization ($mil)	**$226**
Short Interest Ratio (days)	**8.84**
Institutional Ownership (%)	**21**
Insider Ownership (%)	**27**
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 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in '000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	0 A	0 A	0 A	0 A	0 A
2015	0 E	0 E	0 E	0 E	0 E
2016					0 E
2017					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.28 A	-$0.21 A	-$0.16 A	-$0.30 A	-$0.96 A
2015	-$0.36 A	-$0.34 E	-$0.24 E	-$0.26 E	-$1.22 E
2016					-$0.92 E
2017					-$0.81 E

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

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WHAT's NEW…

Q1 Results, Operational Update: TARGT$_{EPO}$ Extends Efficacy Duration, PD Trial Underway, CHOP Opportunities…

Medgenics reported first quarter financial results and revealed additional positive progress of the ongoing dose-ranging clinical trial in ESRD patients. The company also provided an update on the status and plans for their other previously disclosed development programs which includes other EPO-related targets and a GLP platform. In addition, management talked further about their new collaboration with CHOP and the vast potential this database could provide in terms of discovering other orphan and rare disease targets which may be able to be effectively treated with their TARGT Biopump technology. We characterize both the clinical and operational update as highly encouraging with positive developments on both fronts and no significant adverse surprises which further bolsters our outlook and opinion that the shares remain priced at an attractive entry point.

Q1 operating expenses were $7.9M, slightly lower than our $8.2M estimate but up considerably from $5.2M in the year-earlier period, mostly due to ramping R&D activity as well as higher stock-based compensation in the most recent quarter. Net loss and EPS, excluding non-cash revaluation of warrant liabilities (which increased significantly with the ~60% growth in the stock price during Q1), was $7.9M and ($0.32), largely in-line with our $8.1M and ($0.34) estimates.

Cash used in operating activities was $8.1M but, excluding changes in working capital, this was $4.7M. Cash balance at the close of Q1 was $25.2M.

MDGN-201 Update: *No new drop-outs, one patient now stable through 10 months, mid-dose now enrolling…*

As a reminder, MDGN-201 is the study using TARGT$_{EPO}$ with a new generation vector to produce natural erythropoietin in patients with chronic kidney disease and end-stage renal disease. Goal of the trial is to maintain hemoglobin in a pre-defined range (9g/dl - 12g/dl) for more than six months. It is dose-escalating with up to 18 patients (three cohorts of up to six patients each). Patients are removed from ESAs after a run-in period. Following reimplantation of TARGT$_{EPO}$ rescue recombinant EPO will not be used until TARGT$_{EPO}$ stops producing natural EPO.

Management has provided ongoing updates on progress of the study which included the most recent prior update in mid-February. At that time all six low-dose patients had been enrolled and implanted with TARGT$_{EPO.}$ While two of the six had been removed from the study, the other four showed stable hemoglobin levels including one patient that had been treated for eight months.

Of the two drop-outs, one required rescue recombinant EPO, although this was not until five months post-implantation. Given that this patient was implanted with only two TARGT$_{EPO}$ micro-organs (in the lowest-dose cohort) that five month duration before requiring rescue EPO is very encouraging for the potential efficacy of TARGT$_{EPO.}$ And the other patient that was removed from the study, which was two months after implantation, required rescue EPO following surgery which was unrelated to the TARGT therapy.

So as of mid-February four of the six low dose patients remained in the study with stable hemoglobin levels within the target range. Patient 1 (3 TARGT$_{EPO}$ implanted) was stable through eight months, patient 4 (2 TARGT$_{EPO}$ implanted) was stable through four months, patient 5 (3 TARGT$_{EPO}$ implanted) was stable through three months and patient 6 (3 TARGT$_{EPO}$ implanted) was stable through two months.

The most recent update, provided on the Q1 earnings call last Friday (4/17), revealed that all four of these patients remained in the study. Patients 1, 4 and 6 remained at stable hemoglobin levels through 10 months, 6 months and 4 months, respectively. Patient 5 remained in the study through 5 months although was under evaluation as he had refused 3 of 4 depo-medrol injections which is a violation of the trial protocol.

Most Recent Data, From Q1 Conference Call on April 17th

Summary Patient Status – Low Dose Cohort

Subject #	Age	Gender	Dialysis (years)	Medical History	rHuEPO Run-in Dose (IU/wk)	# of TARGTs	Months Post Implant	Status
E101	70	M	4	hypertension, diabetes	12K	3	10	Ongoing; stable Hb
E102	26	M	0.8	hypertension, IgA nephropathy	12K	2	5	Returned to baseline; received rHuEPO. Exited study.
E201	74	F	1.4	hypertension, diabetes, stroke	20K	1	2	Required rHuEPO following surgery unrelated to therapy. Exited study.
E202	76	M	9	hypertension, stroke, MI	20K	2	6	Ongoing; stable Hb
E203	67	M	1	diabetes	20K	3	5	Ongoing; under evaluation*
E204	64	F	0.75	hypertension	8K	3	4	Ongoing; stable Hb

* Patient refused 3 out of 4 Depo-Medrol injections

We continue to characterize the results as highly promising with growing encouragement as hemoglobin remains stable with longer duration of the study. With one patient now at 10 months and another through 6 months, there is firming validation of TARGT efficacy. And with no treatment-related adverse events, safety has not been an issue.

Mid-dose enrollment has commenced. Similar to the low-dose group, the mid-dose cohort will include up to six patients. While the low dose consisted of $TARGT_{EPO}$ in the range of 15-25 IU/kg/day, the mid-dose cohort will receive EPO of 35-45 IU/kg/day. Two mid-dose patients are now enrolled with all six expected to enter the study by mid-year. The expectation is that this mid-dose cohort may experience greater duration of effect within the target hemoglobin range.

Update on Other EPO-Related Programs: *PD Initiated in Israel, IND Filed, MDS Timeline Slightly Delayed…*

As a reminder, last October MDGN announced that they expected to pursue several indications related to $TARGT_{EPO.}$ Those being (also see chart below):

- ESRD patients that are hypo-responsive to ESAs - a U.S. population that the company estimates at approximately 40k - 70k
- Beta Thalassemia, a rare blood disorder associated with anemia (i.e. - low hemoglobin) and low levels of EPO. The company estimates that there are ~16k people in the U.S. and Europe combined that suffer from Beta Thalassemia.
- anemic CKD patients which are candidates for transplant - a population MDGN estimates at about 10k in the U.S.
- peritoneal dialysis patients – estimated at about 20k people in the U.S.
- myelodysplastic syndrome – about 60k people in the U.S.

Potential Orphan Indications for $TARGT_{EPO}$

INDICATION	PATIENT / PAYOR NEED	CLINICAL RATIONALE	ESTIMATED PREVALENCE
PERITONEAL DIALYSIS (PD)	PD provides 20% cost reduction vs hemodialysis	Improved compliance will boost outcomes and reduce costs for PD patients	20,000 (US)[5]
ANEMIC CKD TRANSPLANT CANDIDATES	Heightened immunogenic profile due to repeat transfusions	Reduced transfusions will prevent increased immunogenicity, shorten wait times and improve transplant outcomes	10,000 (US)[5]
HYPO-RESPONDERS TO rHuEPO	Unable to manage anemia on high doses of rHuEPO; often leading to hypertension	Continuous, physiologic levels of eEPO will stimulate bone marrow more effectively and safely than intermittent IV dosing[5]	40,000 – 70,000 (US)[5]
MYELODYSPLATIC SYNDROMES (MDS)	20-55% of MDS patients respond to rHuEPO but use limited due to safety concerns[3]	Reduced need for transfusions would limit iron overload	60,000 (US)[4]
BETA THALASSEMIA INTERMEDIA	Requires frequent transfusions (up to 12 per annum)	rHuEPO shown ability to raise Hb in beta thalassemia[1]; safety concerns limit use	15,000 (US/EU)[2]

MDGN has already made meaningful progress towards moving these programs along. This includes the recent initiation of a peritoneal dialysis (PD) clinical study in Israel and the filing of an IND seeking approval to initiate clinical studies in the U.S. The IND will cover PD, anemic transplant patients and hypo-responders. MDGN hopes to have the U.S. study, which will also be dose-ranging, initiated around the middle of the current year.

An Israeli-based myelodysplatic syndrome (MDS) clinical study, previously expected to commence in Q2, has been pushed back to the second half of this year as MDGN locks down regulatory approval to start the study. Beta thalassemia is the last of the already announced EPO-related programs which is expected to begin (pre-clinical) following a meeting with Israeli regulators which should happen in the coming weeks.

GLP Program: *Progress Continues, NPS Pharma May Be Interested…*

Management spent only limited time talking about their GLP-2 program on the Q1 call, only noting that they continue to make progress and, interestingly, that they have been in discussions with NPS Pharmaceuticals (NPSP) which, apparently may have interest in MDGN's GLP-2 program.

As a reminder in October MDGN announced that along with several $TARGT_{EPO}$ indications, they would also pursue, in parallel with the EPO targets, endogenous peptides.

The short half lives of small endogenous peptides provides therapeutic challenges when administered externally - including the need to use high doses and short effect. Since TARGT would produce the peptide naturally and provide a continuous flow (at the "correct" concentration), these challenges could potentially be overcome.

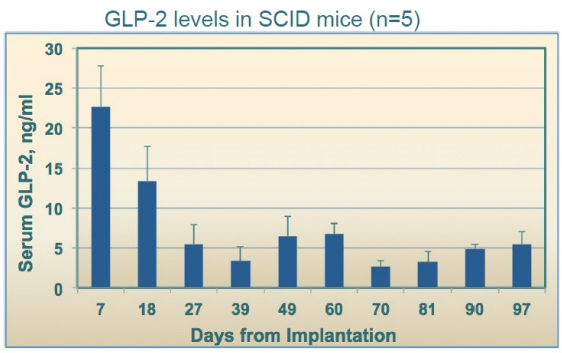
The company's initial focus will be on glucagon-like peptide-2 (GLP-2), which is produced naturally by the intestinal endocrine L cell and certain neurons. It promotes intestinal growth and enhances intestinal function. It's half life is approximately only 5 - 7 minutes. In addition to GLP-2, MDGN expects to pursue several other peptides during 2015.

MDGN expects to target short bowel syndrome, an orphan indication with $TARGT_{GLP-2}$. Short bowel syndrome (SBS) is typically the result of surgical removal of part of the small intestine as a result of a variety of disorders. SBS patients often suffer from malabsorption and may require intravenous nutrition. It is estimated that there are approximately 3k - 5k SBS patients in the U.S.

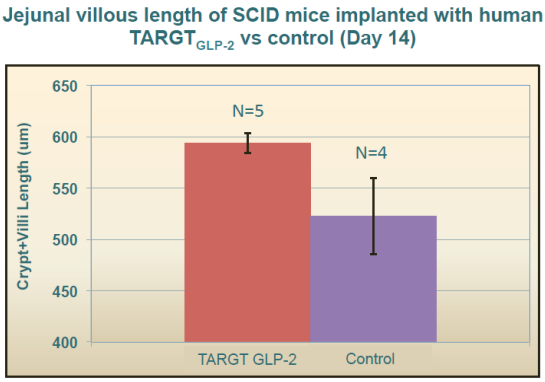
Gattex (teduglutide), marketed by NPS Pharma, is a GLP-2 analog that has orphan designation for SBS and was approved by FDA in late 2012. Gattex promotes intestinal absorption and is dosed once per day via subcutaneous injection. NPS has priced the therapy at approximately $295k per person per year. It is estimated that there are approximately 3k - 5k SBS patients in the U.S. As such the calculated potential market for Gattex is $1B+.

Gattex suffers from certain drawbacks however. Such as being associated with nausea/vomiting, which may be a result of the rapid peak from the bolus injection which is characteristic of injected peptides. $TARGT_{GLP-2}$ could potentially eliminate or reduce peaks and troughs and potential related health risks associated with bolus injections. Development of $TARGT_{GLP-2}$ is in preclinical stage and has been used in mice which showed secretion of GLP-2 for a term of 100 days.

At the January 2015 Biotech Showcase presentation MDGN announced SCID mouse data of GLP-2 following 100 days after implantation which indicated the micro-organ has been able to produce GLP-2 through 100 days with only a slight peak through about the first two weeks. Also presented was SCID mouse data versus sham control which demonstrated a biological effect of the GLP-2 micro organ (data was through two weeks).



TARGT system has demonstrated the unique ability to produce peptides *in vivo*



Significant Potential Opportunities from CHOP…

Management is clearly excited over the potential orphan / rare disease targets that could materialize from the massive CHOP (The Children's Hospital of Philadelphia) genetic database. The collaboration with CHOP was just consummated in November of last year and MDGN has already made substantial headway in weeding through the database and with identifying potential areas of interest. CHOP offers not only the potential to massively broaden the scope and depth of potential targets,it also offers the opportunity to significantly shorten the development and eventual commercialization timeline.

As management explained on the call, they (and their colleagues at CHOP) believe there is real potential to exploit orphan / rare disease targets that are already supported by animal models but may have failed in human studies based on a variety factors, including non-optimal study populations. MDGN's process is to lead with genomic view in order to more specifically identify and characterize initial candidates and then drill down through a progressive approach to identify the cause of a particular disease and narrow down potential therapeutic options. The company believes applying this approach can reduce the time that it takes to get a candidate from development inception to regulatory submission from a typical average of ten to fifteen years to just five or six years. Management laid out certain criteria that they will use in helping identify areas of interest and to aid in narrowing their focus. Initial candidates could be identified sometime later this year.

CNS Targets…

MDGN recently entered into a collaboration with Harvard University to explore potential opportunities of their technology in central nervous system disorders, an area that has proven difficult to treat with traditional drugs. Development is still in pre-clinical.

Maintaining Outperform Rating

We remain ever-more encouraged with the data coming from the MDGN-201 clinical trial. At least three (and possibly four) of the six lowest-dose cohort patients appear to have been effectively treated with $TARGT_{EPO}$ through at least four months, including one patient through six months and another through ten months. In

addition, hemoglobin levels have been maintained in the target range with no serious treatment related adverse events. Mid-dose enrollment has commenced with full enrollment expected towards mid-year. Mid-dose may show longer duration of efficacy and may provide even greater insight into the utility of $TARGT_{EPO}$ and MDGN's micro-organ technology.

Data from additional studies, which could be available later this year, could provide even more information on the utility of the TARGT technology. PD trial is now underway in Israel and could begin in the U.S. by summer. MDS study could also be up and running in Israel in the coming months. The GLP-2 program, while still in preclinical studies, has shown initial promise and has spurred interest from NPS Pharma. The CHOP relationship should provide an accelerated and broadened pathway in development of these and (almost certainly) additional, yet-to-be announced, orphan targets. MDGN is continuously and rapidly increasing the number of shots on goal and following their low-risk strategy.

We are maintaining our Buy rating.

VALUATION

Given the early stage of the company along with various uncertainties that are inherent of most development stage companies, valuation is less than straightforward. We think the most reasonable methodologies are to look at a pure-play development stage orphan drug company and DCF valuation based on annual revenue of an "average" orphan drug.

Comparable Methodology ~ $300M Market Value

Synageva BioPharma (GEVA) is developing sebelipase alfa (SBC-102), an orphan-designated compound for lysosomal acid lipase deficiency. The market for SBC-102 has been estimated at approximately $600M per year. The company went public in 2011 with the stock commencing trading in July 2011. In December 2011 GEVA completed enrollment of their phase I/II study for SBC-102 - at that time the company had an approximate $310M market value. GEVA's current market cap is $4.0B.

We think it is reasonable to equate MDGN's current product development status with that of GEVA's when enrollment had completed for SBC-102 and when the company traded at a market value of ~$300M. While MDGN has yet to commence enrollment for a specific orphan designated clinical trial, we think their development status is comparable for several reasons. $TARGT_{EPO}$ has demonstrated efficacy (with no safety concerns) in phase I/II trials. Preliminary clinical data from MDGN-201, including one patient treated with EPO micro-organ for ten months, is highly encouraging. And while $TARGT_{EPO}$ is not yet orphan-designated, the TARGT technology had already received orphan designation for INFRADURE - as such, it is conceivable it could receive orphan designation for other targets.

"Average" Orphan Company Value ~$250M

We also use an "average" orphan company valuation methodology based on statistics from a report done by Thomson Reuters Life Sciences Professional Services and Pfizer. According to that study, the average per-year revenue of orphan drugs is approximately $600M. We have built a DCF model that more conservatively assumes $450M of revenue is generated over the remaining patent life of one orphan designated Biopump product. Other assumptions are that this product launches in 2020 (we think 2018 or 2019 launch is also reasonable), has 14 - 15 years of patent life remaining, revenue falls 50% per year each year after patent expiration and, given the high selling prices of orphan drugs, commands gross margins of 80% - 85%. We estimate operating expenses at just 20% of revenue given that orphan drugs can typically be detailed with a small sales force and relatively little overall marketing support. Using a 10% discount rate values the company at approximately $1.1B. Discounting this by the ~22% probability (per Thomson study) that an orphan drug in phase I eventually is approved, values the company at approximately $250M.

Valued MDGN at $275M, But We Think $300M is Now More Appropriate

Average of these two methodologies puts the value of MDGN at approximately $275M. While we had been valuing MDGN using the $275M average of these two methodologies, we feel the substantive progress and highly encouraging results of the MDGN-201 study, coupled with the vastly and rapidly increased number of potential other orphan indications that have recently come online warrant using the $300 million comp as a more reasonable valuation for MDGN.

We also think that there is potential additional value from the possibility of licensing $TARGT_{EPO}$ for the broader CKD/ESRD population which is not considered in this figure. We also note that this $275M valuation only assumes eventual approval for one orphan indication. As explained in the Thomson study, the value of drugs which were indicated for more than one orphan disease were about four times as great as those indicated for only one orphan disease.

We value the company at $300M or approximately $12/share. Further successful progression through the development pathway should provide for additional de-risking and potential upside to our current $12/share target price.

FINANCIAL MODEL

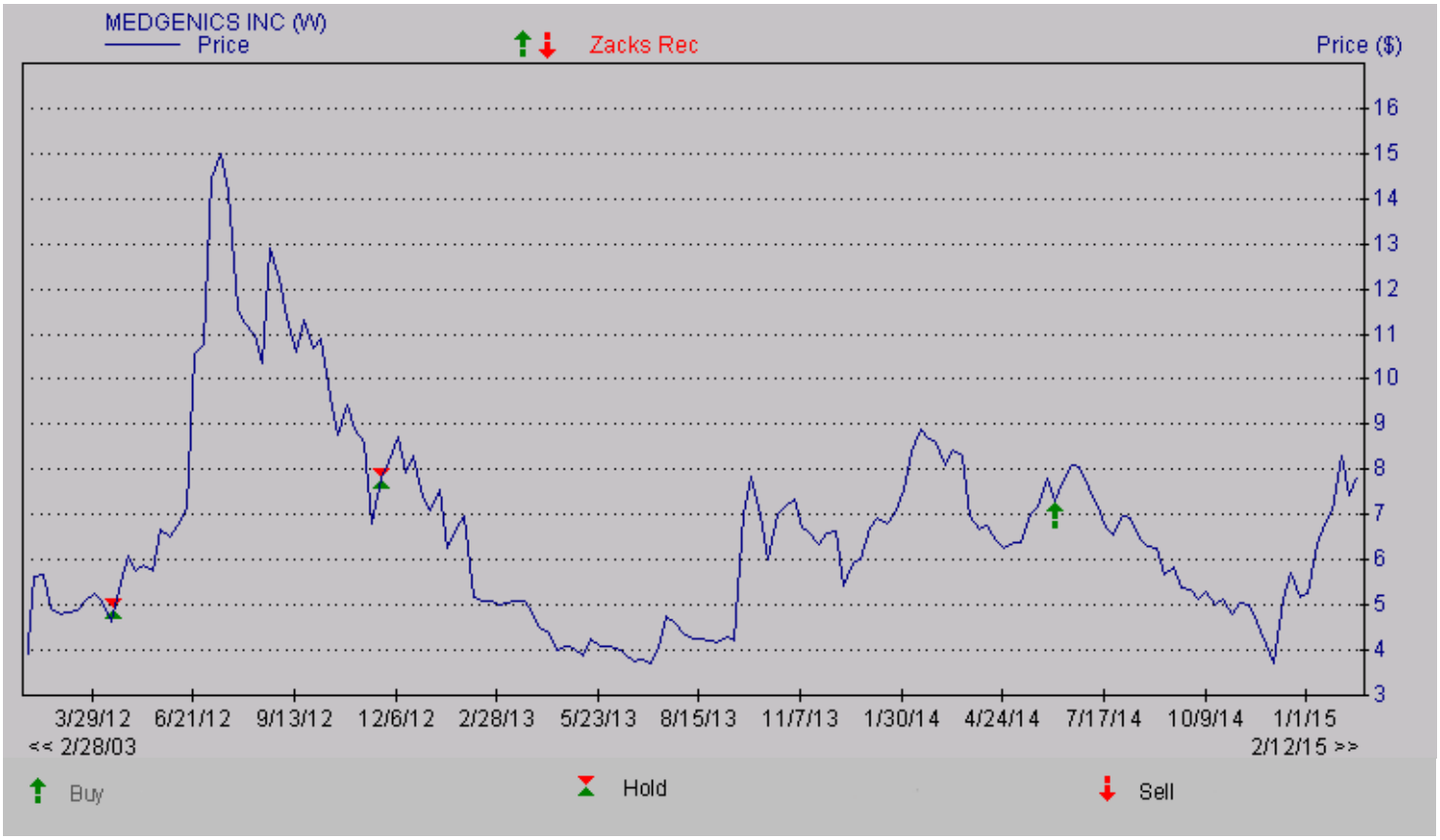
Medgenics, Inc.

	2014 A	Q1A	Q2E	Q3E	Q4E	2015 E	2016 E	2017 E	2018 E
Total Revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-	-	-	-
Cost of Goods Sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Margin	-	-	-	-	-	-	-	-	-
SG&A	$10,686.0	$3,947.0	$3,103.0	$2,787.0	$2,901.0	$12,738.0	$12,801.0	$13,366.0	$13,080.0
% SG&A	-	-	-	-	-	-	-	-	-
R&D, net of grants	$8,253.0	$3,901.0	$5,414.0	$3,620.0	$3,724.0	$16,659.0	$12,077.0	$11,240.0	$10,805.0
% R&D	-	-	-	-	-	-	-	-	-
Operating Income	($18,939.0)	($7,848.0)	($8,517.0)	($6,407.0)	($6,625.0)	($29,397.0)	($24,878.0)	($24,606.0)	($23,885.0)
Operating Margin	-	-	-	-	-	-	-	-	
Financial expense, net	$518.0	($1,073.0)	$50.0	$40.0	$25.0	($958.0)	$47.0	$0.0	$0.0
Total Other Income (Expense)	$518.0	($1,073.0)	$50.0	$40.0	$25.0	($958.0)	$47.0	$0.0	$0.0
Pre-Tax Income	($18,421.0)	($8,921.0)	($8,467.0)	($6,367.0)	($6,600.0)	($30,355.0)	($24,831.0)	($24,606.0)	($23,885.0)
Tax expense (benefit)	$12.0	$1.0	$0.0	$0.0	$0.0	$1.0	$0.0	$0.0	$0.0
Tax Rate	*-0.1%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($18,433.0)	($8,922.0)	($8,467.0)	($6,367.0)	($6,600.0)	($30,356.0)	($24,831.0)	($24,606.0)	($23,885.0)
YOY Growth	*24.4%*	*-47.9%*	*58.2%*	*65.8%*	*117.2%*	*64.7%*	*-18.2%*	*-0.9%*	*-2.9%*
Net Margin	-	-	-	-	-	-	-	-	-
EPS	($0.96)	($0.36)	($0.34)	($0.25)	($0.26)	($1.22)	($0.92)	($0.81)	($0.77)
YOY Growth	*-4.9%*	*36.8%*	*83.5%*	*30.9%*	*-4.0%*	*27.0%*	*-24.7%*	*-11.6%*	*-4.8%*
Diluted Shares O/S	19,247	24,844	24,910	25,000	25,080	24,958	27,110	30,400	31,000

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Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 15.3%, Hold/Neutral- 76.8%, Sell/Underperform – 7.2%. Data is as of midnight on the business day immediately prior to this publication.