Zacks Small-Cap Research

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# Medgenics Inc (MDGN-AMEX)

**MDGN: 201-Study Patient Stable Through 13 Months, Mid-Dose Enrolling. Maintaining Buy Rec**

| | |
|---|---|
| **Current Recommendation** | **Buy** |
| Prior Recommendation | N/A |
| Date of Last Change | 06/08/2014 |
| Current Price (08/11/15) | $8.04 |
| **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** | **$3.68** |
| **One-Year Return (%)** | **40.00** |
| **Beta** | **-0.38** |
| **Average Daily Volume (sh)** | **205,697** |
| **Shares Outstanding (mil)** | **25** |
| **Market Capitalization ($mil)** | **$201** |
| **Short Interest Ratio (days)** | **4.90** |
| **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 A | 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 | -$0.24 A | -$0.29 E | -$0.28 E | -$1.17 E |
| 2016 | | | | | -$1.03 E |
| 2017 | | | | | -$0.86 E |

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

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## WHAT's NEW…

**Q2 Results, Operational Update:**
Medgenics reported second quarter financial results and provided an update on their development programs. The MDGN-201 study has completed enrollment of the low-dose cohort (n=6) and continues to enroll in the mid-dose cohort (3 patients so far). One patient remains stable in the low-low dose cohort (through 13 months) and two of the three mid-dose patients enrolled so far remain stable. The peritoneal dialysis study just recently initiated in both Israel and the U.S. with two patients now enrolled. MDGN also expects to initiate smaller proof-of-concept studies during the current year in other renal indications.

Q2 operating expenses were $6.9 million, well below our $4.3 million estimate. The difference largely reflects OCS grant (~$3.4M over 12/14 – 12/15) which we had yet to incorporate into our model and which reduced gross R&D expense by $1.4 million in Q2. Net loss and EPS, were $6.1 million and ($0.24), compared to our $8.5 million and ($0.34). The difference, again, mostly reflecting the benefit from the OCS grant. We model the remainder of the grant to be realized in 2H 2015.

Cash used in operating activities was $3.5 million. Excluding changes in working capital this was $4.1 million. Cash balance at Q2 quarter end was $22.0 million. The company expects current cash to fund operations through Q3 2016, which is consistent with our model assumptions.

***MDGN-201 Update:*** *Low-Dose Patient Stable Through 13 Mths, 2 Mid-Dose Patients Remain Stable…*

MDGN-201 is 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.

**As of June 13th EHA Presentation 3 Low-Dose and 2 Mid-Dose Patients Remained Stable:** MDGN's most recent presentation of the study results was at the 20th Congress of the European Hematology Association (EHA) in Austria on June 13th. At that time all three low-dose cohort patients that had stable EPO secretion and hemoglobin (in predefined target range of 9 - 12 g/dl) as of the last update on April 17th, remained so as of the EHA presentation. This included one patient in the low-dose cohort that had been stable through 11 months post-implantation. The other two patients had been stable for 5 and 7 months.

Patient 5 who as of the mid-April update was still in the study through 5 months was under evaluation at that time as he had refused 3 of 4 depo-medrol injections which was a violation of the trial protocol. He has since been removed from the study.

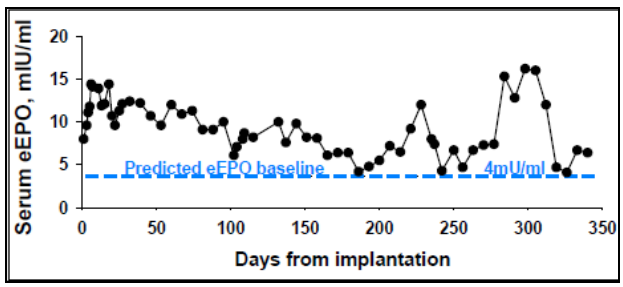
As of the June EHA presentation, of the six patients enrolled in the low-dose cohort, five had now shown a stable response for at least five months.

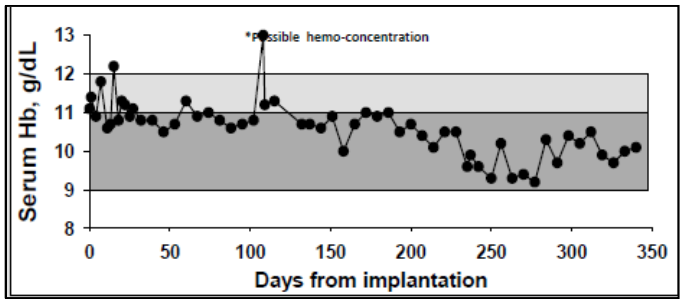
**From June 13th EHA Presentation**

| Low Dose Patients Summary | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Subject # | Age | Gender | Dialysis (years) | Medical History | rHuEPO Run-in Dose (IU/wk) | # of TARGTs | Months Post Implant | Status |
| E101 (Patient 1) | 70 | M | 4 | hypertension, diabetes | 12K | 3 | 11 | Ongoing; stable Hb |
| E102 (Patient 2) | 26 | M | 0.8 | hypertension, IgA nephropathy | 12K | 2 | 5 | Returned to baseline; received rHuEPO. Exited study. |
| E201 (Patient 3) | 74 | F | 1.4 | hypertension, diabetes, stroke | 20K | 1 | 2 | Required rHuEPO following surgery unrelated to therapy. Exited study. |
| E202 (Patient 4) | 76 | M | 9 | hypertension, stroke, MI | 20K | 2 | 8 | Ongoing; stable Hb |
| E203 (Patient 5) | 67 | M | 1 | diabetes | 20K | 3 | 6 | Returned to baseline; received rHuEPO. |
| E204 (Patient 6) | 64 | F | 0.75 | hypertension | 8K | 3 | 5 | Ongoing; stable Hb |

**From June 13th Presentation:**

***Patient #1:*** *11 months of TARGT$_{EPO}$ therapy with stable EPO and Hb in target range of 9g/dl - 12g/dl*




Target Hb 9-11

Safety Margin: Hb < 12

The EHA presentation included the first data from the mid-dose cohort, which had at that point enrolled three patients (which is also the current enrollment). Patient 7 had not demonstrated a response to TARGT$_{EPO}$ therapy and was removed. After being removed from the study he also showed poor response to recombinant EPO. Of the other two mid-dose cohort patients, (as of June 13th) one was stable through two months following implantation and the other, which was implanted with TARGT$_{EPO}$ on May 28th, did not yet have data available.

**From June 13th EHA Presentation**

| Mid Dose Patients Summary | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Subject #** | **Age** | **Gender** | **Dialysis (years)** | **Medical History** | **rHuEPO Run-in Dose (IU/wk)** | **# of TARGTs** | **Months Post Implant** | **Status** |
| **E206 (Patient 7)** | 62 | M | 0.7 | Pseudo gout, FSGS, Thalassemia minor | 20K | 3 | <1 | Received rHuEPO. Exited study. |
| **E205 (Patient 8)** | 50 | M | 2 | hypertension, congestive heart failure, diabetes | 16K | 3 | 2 | Ongoing; stable Hb |
| **E401 (Patient 9)** | 66 | M | 4.6 | hypertension, peripheral vascular disease, diabetes | 2K | 5 | N/A | Implanted May 28, 2015; data not yet acquired. |

**Current Update:** While the company provided only a limited update on MDGN-201 with their Q2 earnings release, they did note that one patient remains stable in the low-dose cohort and the remaining two patients in the mid-dose cohort remain stable. MDGN expects to announce additional data at the ESGCT conference in September.

- **Low dose**
  - enrollment completed
  - five of the six patients maintained hgb in targeted range for at least five months
  - all six showed positive response to $TARGT_{EPO}$ therapy at ~100x lower Cmax (exposure) than recombinant EPO
  - one patient remains stable which is now in the 13 month following implantation
  - no treatment related serious events in either the low or mid-dose groups

- **Mid dose**
  - three patients enrolled
  - as noted at the EHA presentation, one patient was removed from the study as he showed poor response
  - two patients remain stable – at approximately 2.5 months and 4 months
  - enrollment continues

***Update on Other EPO-Related Programs:*** *PD Initiated in Israel, U.S, Other Renal Indications to Initiate …*

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)[6] |
| 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 both Israel and the U.S. called **MG-EP-RF-04**.

Goal of the phase II MG-EP-RF-04 open label study is to maintain hemoglobin levels within the targeted range of 9-12 g/dl in peritoneal dialysis patients. It will enroll two cohorts targeting two dose levels; one at 18-25 IU/Kg/day and the other at (35-45 IU/Kg/day). Safety and biological activity, including TARGT$_{EPO}$ secretion measured as EPO levels above baseline, will be assessed.

To-date two patients have been enrolled in MG-EP-RF-04 and both remain stable. In Q2 MDGN received clearance from FDA to proceed with their IND application. The IND will cover PD, anemic transplant patients and hypo-responders.

On the Q1 call management noted that an Israeli-based myelodysplatic syndrome (MDS) clinical study, previously expected to commence in Q2, had been pushed back to the second half of this year as MDGN locks down regulatory approval to start the study. The company did not provide an update on the proposed MDS study in the Q2 earnings release. 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.

While the company has not provided an update to the specific additional renal programs since the Q1 call, they did note in the Q2 earnings release that they expect to initiate small proof-of-concept studies in other renal indications in 2H 2015.

***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.

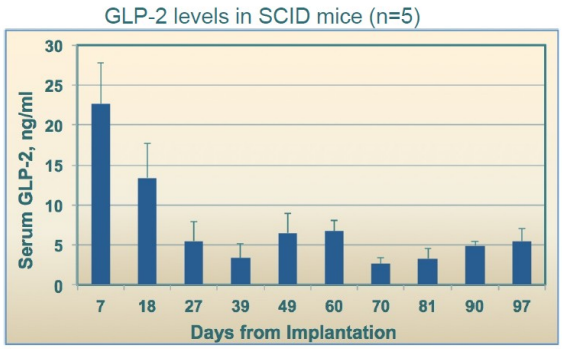
The company's initial focus will be on glucagon-like peptide-2 (GLP-2), which is produced naturally by the intestinal endocrine L cell and certain neurons. It promotes intestinal growth and enhances intestinal function. It's half life is approximately only 5 - 7 minutes. In addition to GLP-2, MDGN expects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

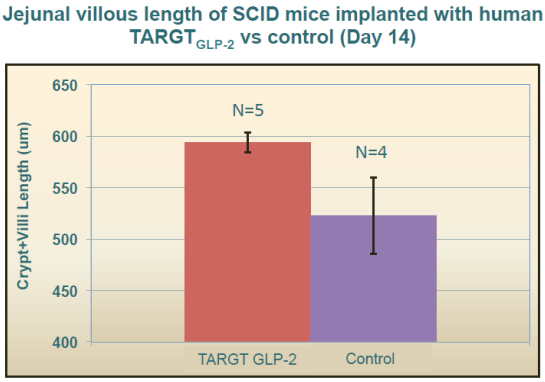
Gattex (teduglutide), marketed by NPS Pharma, is a GLP-2 analog that has orphan designation for SBS and was approved by FDA in late 2012. Gattex promotes intestinal absorption and is dosed once per day via subcutaneous injection. NPS has priced the therapy at approximately $295k per person per year. 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 Q1 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.

## 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 $8.9B.

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 13 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

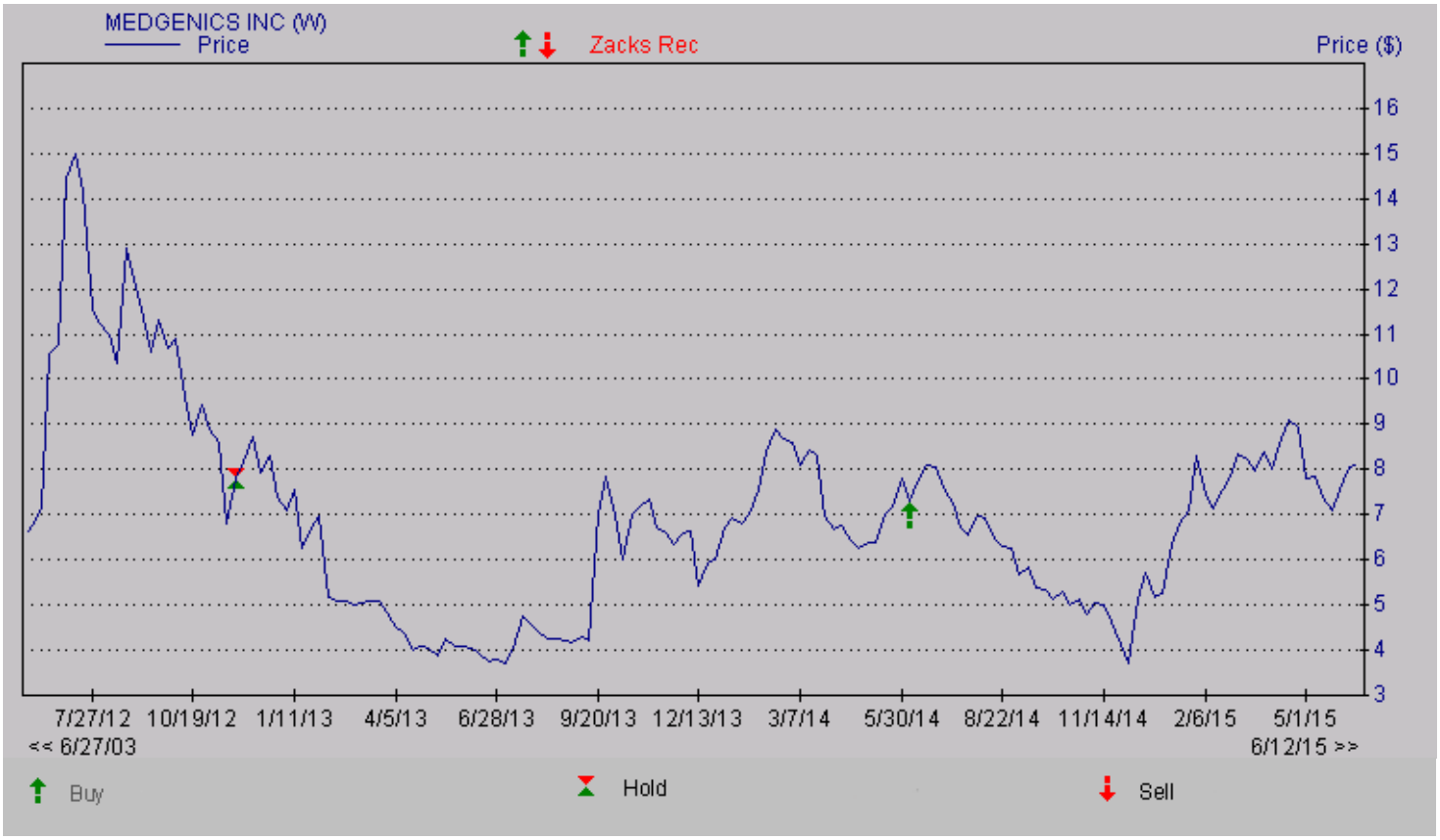
Medgenics, Inc.

| | 2014 A | Q1A | Q2A | 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 | $3,889.0 | $3,940.0 | $3,857.0 | $15,633.0 | $14,655.0 | $14,174.0 | $13,652.0 |
| *% SG&A* | - | - | - | - | - | - | - | - | - |
| R&D, net of grants | $8,253.0 | $3,901.0 | $3,028.0 | $3,365.0 | $3,187.0 | $13,481.0 | $13,421.0 | $12,095.0 | $10,805.0 |
| *% R&D* | - | - | - | - | - | - | - | - | - |
| Operating Income | ($18,939.0) | ($7,848.0) | ($6,917.0) | ($7,305.0) | ($7,044.0) | ($29,114.0) | ($28,076.0) | ($26,269.0) | ($24,457.0) |
| *Operating Margin* | - | - | - | - | - | - | - | - | |
| Financial expense, net | $518.0 | ($1,073.0) | $835.0 | $40.0 | $25.0 | ($173.0) | $47.0 | $0.0 | $0.0 |
| Total Other Income (Expense) | $518.0 | ($1,073.0) | $835.0 | $40.0 | $25.0 | ($173.0) | $47.0 | $0.0 | $0.0 |
| Pre-Tax Income | ($18,421.0) | ($8,921.0) | ($6,082.0) | ($7,265.0) | ($7,019.0) | ($29,287.0) | ($28,029.0) | ($26,269.0) | ($24,457.0) |
| 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) | ($6,082.0) | ($7,265.0) | ($7,019.0) | ($29,288.0) | ($28,029.0) | ($26,269.0) | ($24,457.0) |
| *YOY Growth* | *24.4%* | *-47.9%* | *13.6%* | *89.2%* | *131.0%* | *58.9%* | *-4.3%* | *-6.3%* | *-6.9%* |
| *Net Margin* | - | - | - | - | - | - | - | - | - |
| EPS | ($0.96) | ($0.36) | ($0.24) | ($0.29) | ($0.28) | ($1.17) | ($1.03) | ($0.86) | ($0.79) |
| *YOY Growth* | *-4.9%* | *36.8%* | *24.2%* | *42.9%* | *-2.2%* | *22.5%* | *-11.9%* | *-16.4%* | *-8.7%* |
| Diluted Shares O/S | 19,247 | 24,844 | 24,907 | 25,000 | 25,080 | 24,958 | 27,110 | 30,400 | 31,000 |

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## HISTORICAL ZACKS RECOMMENDATIONS




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