Zacks Small-Cap Research

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DiaMedica Therapeutics (V.DMA-TSX, DMCAF-OTC)

V.DMA: Clinical study of DM199 for CKD planned for 2H18; Phase II Remedy trial of DM199 underway

V.DMA: P/E ratio indicates a fair value at $1.25/share.

Current Price (05/09/18)	$0.55
Valuation	**$**1.25

OUTLOOK

DiaMedica is a clinical stage biopharmaceutical Company. The Company's lead candidate DM199 is a recombinant human tissue kallikrein (KLK1) targeting acute ischemic stroke (AIS) and chronic kidney disease (CKD). The company has reported positive results from a Phase Ib study, has initiated Phase II trial of DM199 for AIS and is preparing for clinical study in patients with CKD caused by Type I/II diabetes.

We are optimistic about the prospects of the Company and hold a fair value at $1.25/share.

SUMMARY DATA

52-Week High	**$0.60**
52-Week Low	**$0.21**
One-Year Return (%)	**N/A**
Beta	**1.62**
Average Daily Volume (sh)	**251,940**
Shares Outstanding (mil)	**157**
Market Capitalization ($mil)	**$88**
Short Interest Ratio (days)	**0.02**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
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 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Growth**
Industry	**Med Products**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of C$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2016	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2017	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2018					0.00 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.01 A	-$0.01 A	-$0.00 A	-$0.01 A	-$0.02 A
2016	-$0.01 A	-$0.01 A	-$0.01 A	-$0.00 A	-$0.02 A
2017	-$0.01 A	-$0.01 A	-$0.01 A	-$0.01 A	-$0.03 A
2018					-$0.04 E

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

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WHAT'S NEW

Update on Fiscal 2017 Financials

There was no revenue recorded in fiscal year ended December 31, 2017.

R&D expenses for fiscal 2017 were $3.27 million, compared to $1.76 million for fiscal 2016.

G&A expenses for fiscal 2017 were $0.90 million, compared to $0.72 million for fiscal 2016.

Net loss for fiscal 2017 was $4.2 million ($0.03 per share), compared to a net loss of $2.2 million ($0.02 per share) for fiscal 2016.

As of December 31, 2017, the company held $1.4 million in cash and cash equivalents.

In March 2018, DiaMedica closed a private placement, which raised **USD$6.3** million in gross proceeds.

DiaMedica issued about 26.5 million units at the price of USD$0.245 (CAD$0.31) per unit, which included both brokered and non-brokered components.

Each unit consists of one common share of DiaMedica and one-half of one common share purchase warrant. Each warrant entitles the holder to acquire one additional common share at an exercise price of USD$0.35 per share in a period of time frame.

The company also closed a non-brokered private placement in December 2017 with gross proceeds of approximately **USD$950,000**.

We welcome these important financings, which not only boost the company's balance sheet, but removes the financing overhang. We believe these new financing will fund the recently initiated Phase II REMEDY study of DM199 for the treatment of acute ischemic stroke and prepare for upcoming clinical study in patients with chronic kidney disease.

Update on CKD Program

Recently DiaMedica announced **positive results** from an in-person Type B meeting the FDA with respect to its planned **clinical trial of DM199** in patients with chronic kidney disease **(CKD).**

The planned clinical study endpoints will include:

- identifying dose(s) of DM199 that may normalize plasma concentrations of KLK1;
- demonstrating the safety and tolerability; and
- evaluating standard measures of kidney function and treatment biomarkers.

Based on the FDA guidance, DiaMedica expects the study to include patients suffering from mild to moderate CKD (stage 3) due to Type 1 and Type 2 Diabetes and is designed to test multiple dosing strategies. Standard measures of safety, DM199 plasma levels and kidney function will be collected before, during and after DM199 treatment.

The company intends to file an **IND application** and expects to initiate a trial in the **2H2018**.

We believe the positive results from the FDA meeting is an important milestone for the company, which will lead to the advancement of DM199 into clinic for the treatment of CKD. The guidance from the FDA provides a path forward to advance the development of DM199 for CKD.

According to National Kidney Foundation, about 30 million adults in the US are estimated to have CKD and roughly 1 in 3 American adults are at risk for this disease.

Worldwide, approximately 1 in 10 people have kidney disease. One in three people in the general population is at increased risk of CKD. An estimated 1 million people die each year from untreated kidney failure. Those with CKD are up to 20 times more likely to die of other causes (mostly cardiovascular disease) before they reach end-stage renal disease.

DM199 is a recombinant form of the human serine protease, KLK1. KLK1 deficiency may play a role in multiple vascular and fibrotic diseases such as chronic kidney disease, retinopathy, stroke, vascular dementia, and resistant hypertension where current treatment options are limited or ineffective.

DM199 represents a novel treatment for patients with a mechanism that is upstream from ACEi, the only approved treatment today for CKD. If approved, DM199 could command a big piece of market share in the rather large CKD market.

New CFO Added to the Management Team

In early April 2018, DiaMedica appointed Mr. Scott Kellen as Chief Financial Officer (CFO) and Corporate Secretary.

Mr. Kellen has held a Certified Public Accountant certificate, and graduated summa cum laude from the University of South Dakota with a Bachelor of Science in Business Administration.

Mr. Kellen has a strong background in financial strategy and reporting and is a highly qualified senior executive with corporate board experience. He previously worked in various roles as COO and CFO with several publicly traded healthcare companies, most recently as CFO for Sun Bio Pharma. Mr. Kellen has significant experience with capital formation, public company reporting and corporate governance.

We believe Mr. Kellen's deep understanding of the financial needs of development stage biotech companies will prove to be invaluable to DiaMedica as the company executes on its growth strategy especially for its clinical programs of DM199.

Partnership will Accelerate the Development of DM199

DiaMedica has been pursuing commercialization partnerships and other strategic initiatives to accelerate the development of DM199.

The company has received several **licensing term sheets** from **Asian pharmaceutical companies** for potential regional licensing rights and the Company is continuing discussions for potential licensing and/or joint venture opportunities.

Recently, DiaMedica entered into a non-binding term sheet with a large **China-based** pharmaceutical company for potential licensing rights in China. The Company is continuing ongoing discussions with potential partners in Asia. Specifically, DiaMedica intends to partner with pharmaceutical and biotechnology companies to conduct Phase III trials, file the appropriate NDA and ultimately market the drug products.

If the Company executes on a definitive agreement it would provide additional non-dilutive funding and further validate its product and the approved crude forms in China and Japan.

We believe a partnership in China/Asia offers great opportunity for DM199 to potentially replace the current KLK1 therapy with an improved recombinant form. A partnership will also help the approval of DM199 in the Asian market. Such a partnership will also boost the company's balance sheet and reduce the capital requirements to conduct Phase III trials.

The company recently announced the appointment of **Dr. Robert Stanton to its Scientific Advisory Board** to support the upcoming clinical trial for chronic kidney disease. Dr. Stanton is Chief of the Kidney and Hypertension Section at Joslin Diabetes Center at Harvard Medical School. The **Company is now preparing for upcoming clinical trial in patients with chronic kidney disease (CKD) caused by Type 1 diabetes**.

Update on REMEDY Phase II Trial of DM199 in Patients with Acute Ischemic Stroke

In September 2017, DiaMedica announced the initiation of its **Phase II REMEDY** clinical trial of **DM199** (recombinant human KLK1) in patients suffering from acute ischemic stroke **(AIS).**

On November 22, 2017, the company further announced that it had received approval from the ethics committee in Australia to initiate the first clinical site for the REMEDY trial.

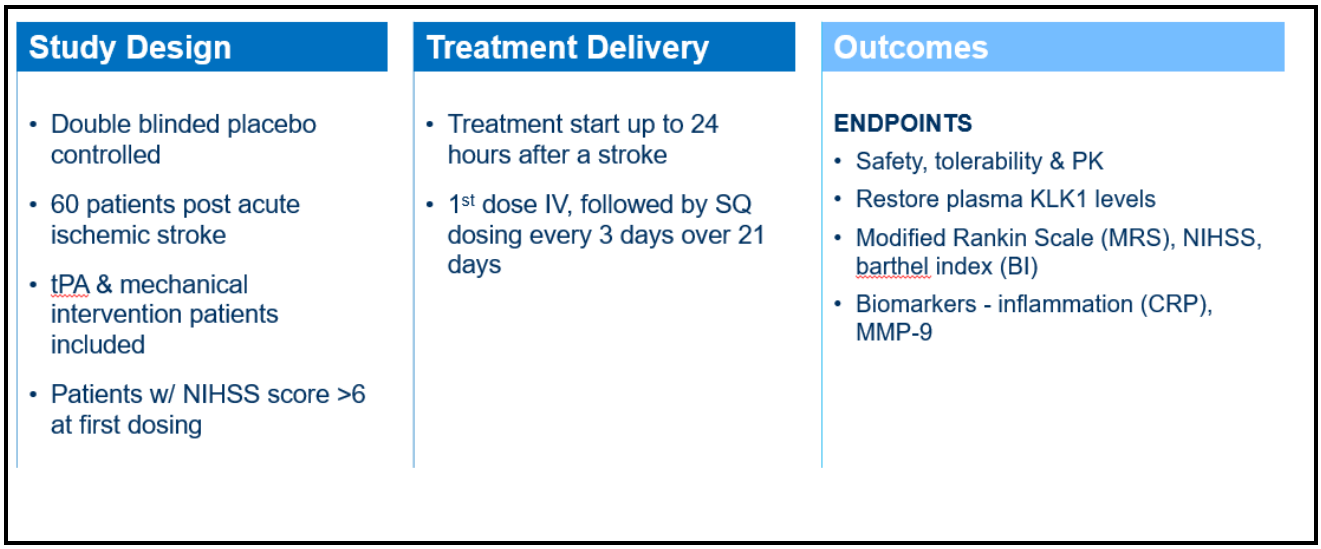
On February 22, 2018, DiaMedica announced the first patient enrollment in the REMEDY trial at the Royal Melbourne Hospital, Melbourne Australia.

The Principal Investigator of the study is Bruce Campbell, MD, MBBS(Hons) BMedSc PhD, FRACP, a neurologist and Head of Hyperacute Stroke in the Department of Neurology, Royal Melbourne Hospital.

Currently two hospitals are recruiting patients and another 8 hospitals are ready to recruit.

The **Phase II REMEDY** trial is a multi-center, double-blind, randomized, placebo-controlled clinical trial which will assess the efficacy and safety of DM199 in patients with a moderate to moderately severe acute ischemic stroke (AIS). DiaMedica intends to enroll approximately **60 patients** with AIS. The patients will be randomized to two groups receiving either DM199 or placebo, which will be administered intravenously (within 24 hours of stroke symptom onset) followed by subcutaneous injections for 21 days.

Safety and tolerability are the primary end points. Secondary endpoints include drug exposure monitoring and a few tests including plasma-based biomarkers and standard functional stroke measures assessed at 90 days post-stroke.to assess DM199's other therapeutic potential.



We think the initiation of the Phase II Remedy trial is a significant step for the development of DM199 for the treatment of AIS.

As we indicated in our previous reports, DiaMedica intends to seek **worldwide** approval of DM199 as a novel therapy for **acute ischemic stroke (AIS).** The company will also position DM199 in **China** as an improved product over the urine-sourced KLK1 protein currently used there. With the potential that effective treatment can be initiated up to 48 hours after the first sign of symptoms, DM199 may fill a large unmet need for stroke patients who cannot receive tPA, benefiting millions of people around the world who currently have limited treatment options.

Positive DM199 Phase Ib Data Reported and Published

In March 2017, DiaMedica reported positive results from its **Phase Ib bridging trial.** The study was designed to compare the profile of DM199 to the approved urinary KLK1 product (trade name Kailikang®) on the market in Asia for acute ischemic stroke (AIS). The reference drug (Kailikang®) is administered intravenously and has a very short half-life.

In early November 2017, DiaMedica announce that the positive data were published in a peer-reviewed journal "International Journal of Clinical Trials".

Background of the Phase Ib Trial

The goal of the **Phase I bridge clinical study** of DM199 was to determine the **safety, optimal dose & delivery.**

The **Phase I** controlled trial was an open-label single ascending study, where healthy volunteers received one of four single doses of DM199 **(n=36),** administered as a 30-minute intravenous **(IV)** or a single subcutaneous **(SQ)** infusion. Plasma DM199 concentration, biomarker concentrations, and other safety and pharmacokinetic parameters were measured in the trial.

In **December 2016**, the company reported positive results from intravenous **(IV)** part of the clinical trial. The study results demonstrated the dose dependent levels of DM199 and identified a dose of DM199 via intravenous **(IV)** administration that produced pharmacokinetic and pharmacodynamic activity that were comparable to those produced by the reference drug, human urinary KLK1 (trade name Kailikang®) approved in Asia.

This clinical study also provided clinically relevant safety data via intravenous delivery of DM199 for the first time at dose levels comparable to the currently approved human urinary KLK1 product.

No treatment limiting adverse events were reported in any dose group. A few patients experienced mild orthostatic hypotension which is consistent with the mechanism of action and demonstrated drug activity. The Company plans to publish the full results of the study in a peer reviewed journal.

The Updated Result from the SC Part of the Phase Ib Trial

The Company has reported an improved **subcutaneous (SC) dose** of DM199 producing sustained plasma levels **superior to** the reference drug.

The DM199 SC delivery provides sustained levels of the KLK1 protein, offering a potentially superior profile to the reference drug, which has a very short exposure window. The dosing of DM199 will be significantly more convenient and potentially provide improved efficacy to the short half-life of the reference drug. DM199 has the same amino acid sequence as the reference drug, identical biochemical activity, and demonstrated similar physiological effects.

No treatment-limiting adverse events were reported in any dose group. The Company plans to publish the full results of the study in a peer reviewed journal.

The Implications

- **More frequent delivery could improve efficacy:**
  - Kailikang® has very short half-life potentially limiting efficacy;
    - Administered 1 times/day 50-minute slow infusion;
    - KLK1 levels decline quickly after infusion;
    - 1 times/day IV dosing may not be enough KLK1 in system for optimal efficacy;
    - **1 vs. 3 times/day dosing** IV urinary KLK1 clinical trial study recently initiated;

- **IV DM199 delivery**
  - DM199's very low manufacturing cost will support economics of increased dosing frequency

- **SQ DM199 delivery**
  - Significantly longer half-life vs. IV Kailikang®
  - Promote elevated KLK1 levels throughout the day, not just after infusion
  - Support full 21-day treatment regimen at home – delivery every 1 to 3 days
  - Today, many patients in China do not come back to hospital for daily 50-minute slow infusion affecting efficacy and sales.

The Phase Ib trial has identified the optimal dosing of DM199, **both IV and SQ** compared to the Kailikang® (urinary KLK1). Kailikang® is administered via IV for 50 minutes daily for 21 days. The challenge is that within minutes of stopping the slow infusion, KLK1 drops right off. A single SQ dose of DM199 maintains KLK1 levels for 3 days thus supporting less frequent dosing and more importantly anticipated increased efficacy by having KLK1 levels elevated for the full day instead of just during the infusion period and minutes after stopping the infusion with Kailikang®.

The company is also leveraging the existing efficacy and understanding of Kailikang® by over 400,000 patients who have received treatment to date. Thus, efficacy can be improved by using the company's long acting SQ delivery, targeting patients with greatest likelihood to respond, targeting patients with lower KLK1 levels and shortening the treatment window from the 48 hours approved by Kailikang® while still capturing more stroke patients.

Attractive Valuation

We maintain our optimism of DMA's long-term prospect and reiterate our fair valuation for the company at $1.25/share.

DiaMedica is a clinical-stage biopharmaceutical company with a current focus on acute ischemic stroke **(AIS)** and chronic kidney disease **(CKD).** The company's lead candidate is **DM199**, a recombinant human tissue kallikrein (KLK1). DiaMedica is developing DM199 for the treatment of AIS and CKD, two large markets with huge unmet medical needs.

The only **FDA approved** treatment for acute ischemic strokes **(AIS)** is tissue plasminogen activator (**tPA**, also known as IV rtPA). tPA works by dissolving the clot and improving blood flow to the part of the brain being deprived of blood flow. If administered within 3 hours (and up to 4.5 hours in certain eligible patients), tPA may improve the chances of recovering from a stroke. However, a significant number of stroke victims don't get the chance to go to the hospital in time for tPA treatment. As a result, only 5-7% patients have the chance to receive tPA treatment.

DiaMedica's **DM199** has the potential to treat AIS patients up to 24 hours post AIS attack due to its unique mechanism of action. DM199 restores blood flow to the ischemic brain region by generating additional bradykinin to activate BK-B2 receptors. Activation of this pair of receptors triggers several important physiological responses that could be beneficial following AIS.

For chronic kidney disease **(CKD),** there are no formally approved agents in the US and the EU. Two blood pressure medications angiotensin converting enzyme inhibitors (**ACEi**) and/or angiotensin receptor

blockers **(ARBs**) are widely used and are considered the standard of care. However, both drugs can cause hyperkalemia and angioedema, which leads to only 25% of patients receiving optimal treatment.

DiaMedica is developing DM199 as a **biobetter product** to replace approved Kailikang and porcine KLK1 in Asia and as a **new product** to enter into the US & markets in rest of the world for both AIS and CKD. Since DM199 is recombinant KLK1, which eliminates the side effects of both Kailikang and porcine KLK1. In addition, since DM199 is synthetic, it has unlimited supply and can be manufactured at a very low cost.

We estimate DM199 could be approved in China in 2020 and in the US in 2021. If approved, worldwide peak sales of DM199 for AIS and CKD combined could potentially surpass **$1 billion.**

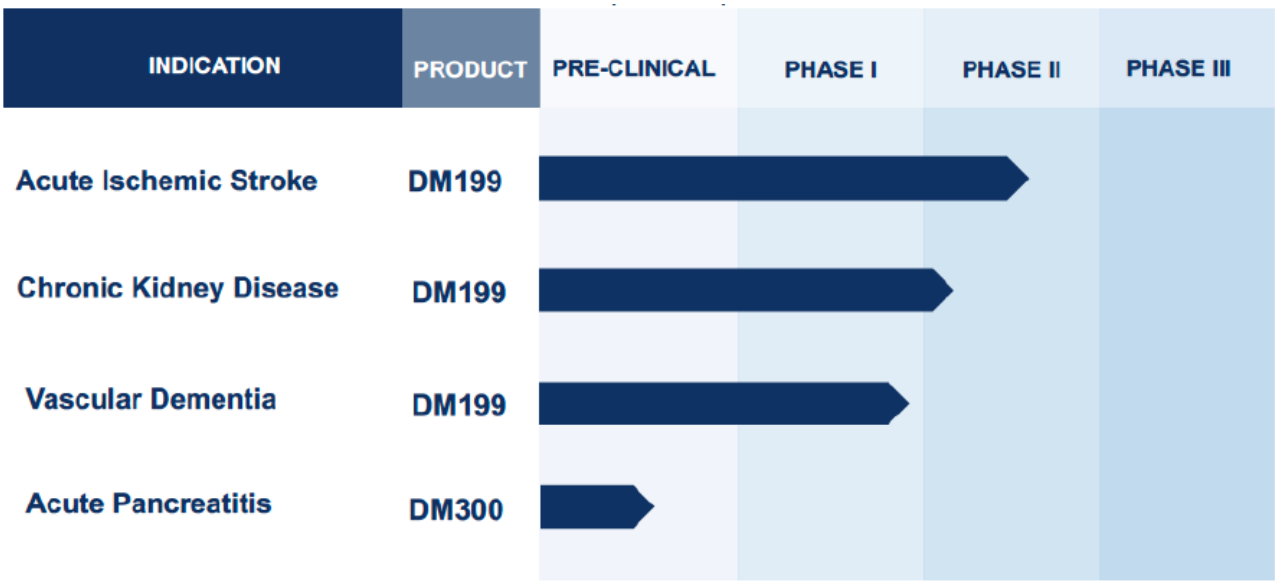
With respect to valuation, we think the current market price does not reflect the Company's true value. Currently, the Company's shares are trading at about CAD$0.56 per share, which values the Company at CAD$88 million in market capitalization based on 157 million outstanding shares. This is a discount compared to its peers. Based on our above discussions, DM199 will be approved in 2020 in China and in the US in 2021 for acute ischemic stroke. We assign a probability of 50% for DM199 stroke and 50% for DM199 diabetic nephropathy for approval at this time. Based on our financial model, DiaMedica will become cash flow positive in 2020 with an EPS of $0.01 based on revenue of $15 million. EPS will grow to $0.21 in fiscal 2022 based on total revenue of $75 million. A 30x P/E multiple and 25% discount rate are used to arrive at our fair value of $1.25 per share. Our price target values the company at $196 million in market cap, which is still conservative in our view.

We believe data is the ultimate driving force to grow a biotech Company. When more positive data are generated from the Company's lead candidate, DM199, and from other early stage candidates, value will be generated for the Company and its shareholders. In this regard, we will keep a close eye on the Company's development plan and update investors on any new data (either clinical or preclinical) generated from its drug candidates.

But keep in mind **the risks**. As we discussed, DiaMedica is still a clinical stage biopharmaceutical company. Our valuation assumes the final approval of its lead candidate DM199 and other candidates. In order for the candidates to reach the market, the Company still needs to overcome both clinical and regulatory hurdles which have proven to be high.

Cash burn is another concern. When DM199 enters into Phase II trials, we expect R&D expenses will also increase. Current cash in hand plus proceeds from recent financing can only support the Company's operations into the end of 2018 according to our financial model. We expect the Company needs to tap the capital market for new funding soon. We reminder investors that equity financing will dilute the existing shareholder base, and could cause the share price to fall.

But generally speaking, we think the stock has a typical high risk/high return profile, which could be part of a portfolio for investors with a high-risk tolerance and relatively long investment horizon.


INDICATION
PRODUCT
PRE-CLINICAL
PHASE I
PHASE II
PHASE III
Acute Ischemic Stroke
DM199
Chronic Kidney Disease
DM199
Vascular Dementia
DM199
Acute Pancreatitis
DM300

INCOME STATEMENT

	2016A (Dec)					2017 (Dec)					2018E (Dec)	2019E (Dec)	2020E (Dec)	2021E (Dec)	2022E (Dec)
$CND in million except per share data	Q1	Q2	Q3	Q4	FYA	Q1	Q2	Q3	Q4	FY	FYE	FYE	FYE	FYE	FYE
R&D revenue	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Product Revenue	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$15.00	$45.00	$75.00
Total Revenues	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$15.00**	**$45.00**	**$75.00**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	200.0%	66.7%
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	2.25	6.75	11.25
Gross Income	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$12.75**	**$38.25**	**$63.75**
Gross Margin	-	-	-	-	-	-	-	-	-	-	-	-	85.0%	85.0%	85.0%
R&D	$0.31	$0.48	$0.97	$0.00	$1.76	$1.16	$0.91	$0.49	$0.71	$3.27	$5.00	$6.00	$7.50	$9.00	$12.00
% R&D	-	-	-	-	-	-	-	-	-	-	-	-	50.0%	20.0%	16.0%
SG&A	$0.17	$0.24	$0.29	$0.02	$0.72	$0.14	$0.19	$0.23	$0.35	$0.90	$1.50	$2.50	$4.00	$5.00	$9.00
%SG&A	-	-	-	-	-	-	-	-	-	-	-	-	27%	11%	12%
Operating Income	**($0.5)**	**($0.7)**	**($1.3)**	**($0.0)**	**($2.5)**	**($1.3)**	**($1.1)**	**($0.7)**	**($1.1)**	**($4.2)**	**($6.5)**	**($8.5)**	**$1.3**	**$24.3**	**$42.8**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	54%	57%
Other Net	$0.0	$0.0	$0.0	$0.2	$0.3	($0.0)	$0.0	($0.2)	$0.1	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	**($0.5)**	**($0.7)**	**($1.2)**	**$0.2**	**($2.2)**	**($1.3)**	**($1.1)**	**($0.9)**	**($1.0)**	**($4.2)**	**($6.5)**	**($8.5)**	**$1.3**	**$24.3**	**$42.8**
Income 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	$0.0	$6.4
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-	-	15.0%
Reported Net Income	**($0.5)**	**($0.7)**	**($1.2)**	**$0.2**	**($2.2)**	**($1.3)**	**($1.1)**	**($0.9)**	**($1.0)**	**($4.2)**	**($6.5)**	**($8.5)**	**$1.3**	**$24.3**	**$36.3**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-	49.8%
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	53.9%	48.5%
Diluted Shares Out	87.3	90.3	110.3	154.1	110.5	110.6	121.1	123.8	154.2	127.4	157.0	160.0	165.0	170.0	175.0
Reported EPS	**($0.01)**	**($0.01)**	**($0.01)**	**$0.00**	**($0.02)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.03)**	**($0.04)**	**($0.05)**	**$0.01**	**$0.14**	**$0.21**
One time charge	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($0.5)**	**($0.7)**	**($1.2)**	**$0.2**	**($2.2)**	**($1.3)**	**($1.1)**	**($0.9)**	**($1.0)**	**($4.2)**	**($6.5)**	**($8.5)**	**$1.3**	**$24.3**	**$36.3**
Non GAAP EPS	**($0.01)**	**($0.01)**	**($0.01)**	**$0.00**	**($0.02)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.03)**	**($0.04)**	**($0.05)**	**$0.01**	**$0.14**	**$0.21**

Source: Company filings and Zacks estimates

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