Zacks Equity Research

September 13, 2010
Ken Nagy, CFA

www.zacks.com
111 North Canal Street, Chicago, IL 60606

# DATATRAK International (DATA.PK-OTC)

**DATA: Zacks Company Report - OUTPERFORM**

| | |
|---|---|
| **Current Recommendation** | **Outperform** |
| Prior Recommendation | Neutral |
| Date of Last Change | 09/09/2007 |
| Current Price (09/10/10) | $1.01 |
| **Six- Month Target Price** | **$3.00** |

## OUTLOOK

DATATRAK International, Inc. is a global technology and services company delivering electronic clinical (eClinical) solutions to support clinical research. Its software suite and service offerings are used to collect, review, report, store and submit to regulatory agencies clinical trial data electronically. While the competition uses an integrated heterogeneous solution (information silos), DATATRAK uses a unified system. The result is seamless communication, optimized data flow and lower costs. The products within the information silos were never designed to work together and "Real time" communications per customers is more like 24 hrs…not bad, but if a patient in site #102 is having an adverse reaction and a similar patient at site #3 has the potential to suffer a similar event…the "not bad" could cost a life.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$1.01** |
| **52-Week Low** | **$0.25** |
| **One-Year Return (%)** | **187.88** |
| **Beta** | **1.66** |
| **Average Daily Volume (sh)** | **5,755** |
| **Shares Outstanding (mil)** | **14** |
| **Market Capitalization ($mil)** | **$13** |
| **Short Interest Ratio (days)** | **0.12** |
| **Institutional Ownership (%)** | **9** |
| **Insider Ownership (%)** | **8** |
| **Annual Cash Dividend** | **$0.00** |
| **Dividend Yield (%)** | **0.00** |
| **5-Yr. Historical Growth Rates** | |
| **Sales (%)** | **-20.9** |
| **Earnings Per Share (%)** | **N/A** |
| **Dividend (%)** | **N/A** |
| **P/E using TTM EPS** | **N/A** |
| **P/E using 2010 Estimate** | **101.0** |
| **P/E using 2011 Estimate** | **25.3** |
| **Zacks Rank** | **N/A** |

| | |
|---|---|
| **Risk Level** | **High,** |
| **Type of Stock** | **Growth** |
| **Industry** | **Comp-Periph Eqp** |
| **Zacks Rank in Industry** | **N/A** |

## ZACKS ESTIMATES

**Revenue**
(in millions of $)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2009 | 2.1 A | 1.83 A | 1.55 A | 1.46 A | 6.94 A |
| 2010 | 1.67 A | 1.88 A | 1.89 E | 1.95 E | 7.43 E |
| 2011 | 2.00 E | 2.02 E | 2.07 E | 2.12 E | 8.22 E |

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

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2009 | -$0.06 A | -$0.01 A | -$0.03 A | -$0.04 A | -$0.14 A |
| 2010 | $0.00 A | $0.00 A | $0.00 E | $0.01 E | $0.01 E |
| 2011 | $0.01 E | $0.01 E | $0.01 E | $0.01 E | $0.04 E |

Zacks Projected EPS Growth Rate - Next 5 Years % **20**

© Copyright 2010, Zacks Investment Research. All Rights Reserved.

## KEY POINTS

- While the competition utilizes an Information Silo and IT integration approach, DATATRAK uses a unified platform. The Silos are limited in terms of communication, upgrades are sluggish, and overall costs are higher.
- Expectations of eClinical market are that it is set to nearly double from 2008 to 2012 and DATATRAK, with its superior product, is poised to capture that growth.
- The firm has growing back log and no debt.

## OVERVIEW

Mayfield Heights, Ohio DATATRAK International, Inc., is a global technology and services company providing the only unified suite of eClinical software delivered in one database and utilizing one user interface providing electronic data capture (EDC), interactive voice response systems, medical coding, web-based randomization, clinical trial management, clinical data management, drug inventory management, digitized electrocardiograms, image collection, viewing and storing capabilities, and workgroup collaboration capabilities. DATATRAK ONE™ is the company's unified clinical approach that includes the cloud based eClinical platform as well as comprehensive consulting, professional services and support following a unified clinical process. DATATRAK and its partners apply this approach to assist customers in the collection and reporting of clinical research data from sites to sponsors and ultimately to regulatory authorities. DATATRAK's vision is to be the clinical enterprise solution to safely accelerate every drug, every biologic and every device ***from concept to cure™.***

### Clinical Research Industry

DATATRAK's customers are sponsor companies and CROs that perform clinical trials in the pharmaceutical, biotechnology, and medical device industries. These industries are driven by regulatory requirements which mandate that new drugs and medical devices be adequately tested in clinical trials prior to marketing these drugs and devices.

Competitive pressures are forcing the pharmaceutical and biotechnology industries to become more efficient when developing new products. To improve returns on research and development investments, pharmaceutical and biotechnology companies are continuing to develop new products, while at the same time attempting to shorten product development timelines. These efforts have placed more drugs into the clinical development process and have increased the pressure for companies to develop products faster in order to maintain growth and continue to achieve acceptable returns on research and development expenditures. Sponsors of clinical trials have attempted to create process efficiencies, control fixed costs and expand capacity by outsourcing clinical research activities.

*"Growing clinical trial complexity continues to challenge the ability of pharmaceutical and biotechnology companies to contain the ever-rising cost of developing new drugs."*

*Tufts Center for the Study of Drug Development

**The old way**

Under the traditional method of clinical research, clinical trial data from each patient is recorded and maintained on paper in a binder, known as a case report form. A separate case report form is maintained for each patient. Clinical research associates then visit research sites to review the clinical trial data for accuracy and integrity. During these visits, known as monitoring visits, the research associate must review each page of each case report form. These visits may last several days, and corrections to the case report forms are frequently required before the data can be delivered to the clinical trial sponsor. Several weeks, or even months, of data may be reviewed during each monitoring visit. At the completion of a monitoring visit, the completed case report form pages are physically transferred to a central location where the data is then entered into a database for statistical compilation. Using this method of data collection and quality control, the duration of the clinical trial process, from patient visit to delivery of clean data to the clinical trial sponsor, can range from six to nine months. Such delays are significant because errors or trends may not be detected until long after the interaction between the patient and clinical investigator.

**Backdrop of Growth**

Expectations of eClinical market are that it is set to nearly double from 2008 to 2012 and DATATRAK, with its superior product, is poised to capture that growth.

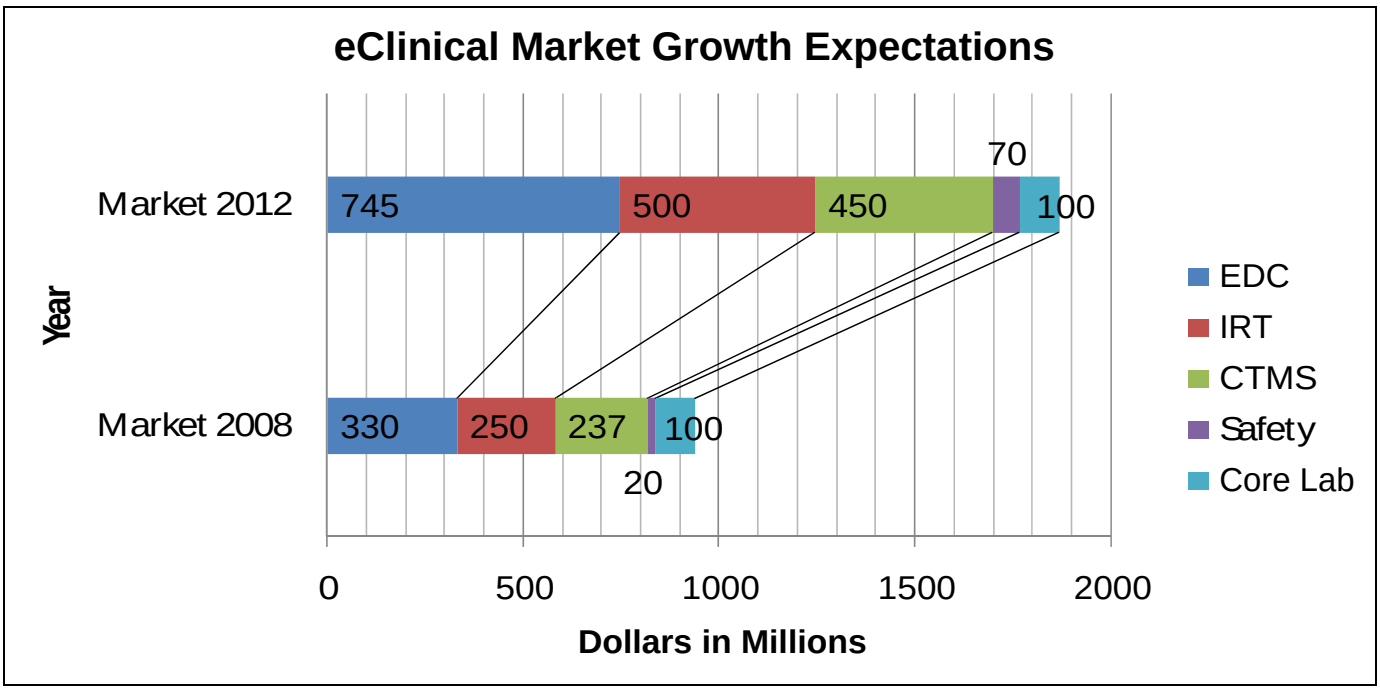
The 2007 EDC market opportunity was roughly $330 million and is expected to increase to roughly $745 million in 2012. The growth rate is 15% per year through 2012.

The IRT Market [Randomization and Inventory Management] was valued at $250 million in 2008 with a growth rate of around 15% a year.

The Safety Market [Coding and PMS] opportunity was approximately $20 million as of 2008 and is expected to grow roughly to $70 million by 2012.

The CTMS Market Size [CTMS] generated revenues of $237.6 million in 2007 and is expected to grow at a rate of 14.5 percent per year until 2014.

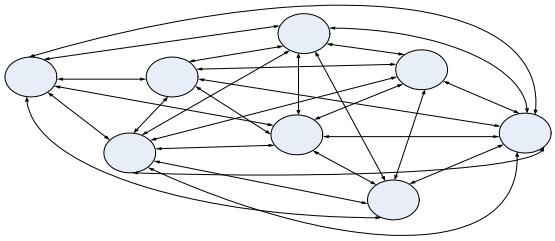
The Core Lab Market [ECGs and Images] is valued at $100 million in 2008



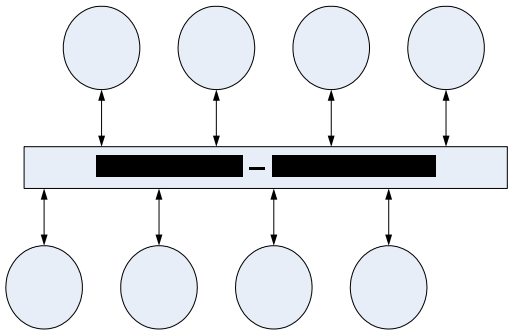
## Unified Solutions versus Integrated.

While acquiring products which creates the information silos and integrated IT approach may provide a short term fix, the result is that integration tends to lead to errors and rising costs from the manual management of data, systems and user accounts. It also leads to multiple vendor contracts which in turn brings up the price. System upgrades tend to be difficult and rare.

**Integrated Solutions**



**Unified Solutions**



Unified solutions on the other hand provide improved usability through one database and one interface. The number of vendors to manage is also reduced and the cost is therefore less. Further the unified system is simply designed with less moving parts and is less susceptible to crashes.

| Integrated | *Unified* |
|---|---|
| Silos of Automation | One System |
| Silos Never Intended / Designed to Talk | Seamless Module Communication |
| Silos Built Independently | Common Vendor, Common Technology |
| Silos need Bridges to Communicate | One Underlying Framework |
| Bridges Limit Data Traffic | Optimized Data Flow |
| Susceptible to Crashes and Bugs | Fewer Moving Parts = Fewer Problems |
| Promise of Real -Time Data Visibility Often Not Delivered | Data Always Visible |
| Increased Maintenance Costs | Lower Maintenance Costs |
| Process Reengineering Hard | Process Reengineering Easy |
| Higher trial budget costs | Lower trial budget costs |

**Attracting Attention**

On June 23, 2010 Phase Forward Incorporated (PFWD ), a leading provider of data management solutions for clinical trials and drug safety, announced that it had agreed to merge with Oracle Corporation ("Oracle") and Pine Acquisition Corporation, a Delaware corporation and a wholly-owned subsidiary of Oracle. Phase Forward is a leading provider of integrated data management solutions for clinical trials and drug safety. Phase Forward's products and services have been utilized in over 10,000 clinical trials involving more than 1,000,000 clinical trial study participants at over 300 organizations and regulatory agencies worldwide including. This $685 million deal creates a significant competitor but it also legitimizes the growth potential of the space and shows the strategic importance of the industry.

From our perspective the firm appears to be firing on all cylinders. DATA has a growing backlog, a debt free balance sheet, and is expanding in Asia and Europe. The second quarter of 2010 represented the fourth consecutive quarter-over-quarter increase in backlog. Backlog increased from $9.5 million at December 31, 2009 to $10.9 million at June 30, 2010. DATATRAK and NTT DATA entered into an agreement to allow NTT DATA to sell Enterprise Transfer services within the Japanese market NTT DATA entered into its first third-party multi-year Enterprise Transfer agreement producing additional revenue streams for both NTT DATA and DATATRAK.

## INDUSTRY OUTLOOK

INDUSTRY OUTLOOK - Positive

The outlook for the software industry is positive. The last few quarters have shown signs of demand stabilization and cost cutting initiatives. While areas like enterprise resource planning systems, supply chain management software, and customer relationship management software have been hit hard by weak IT spending, other niches have held up relatively well. These include gaming, video editing and security software. Government spending as well as health care also has been supportive to the software industry.

With several important software categories reaching maturity, top-line growth for the industry is likely to remain below historical levels, even after the industry recovers. Nevertheless, long-term growth prospects are still modestly above average. In addition, several of the group's top companies possess stellar fundamentals, including high profit margins, pristine balance sheets and cash flow well in excess of capital requirements.

## INDUSTRY POSITION

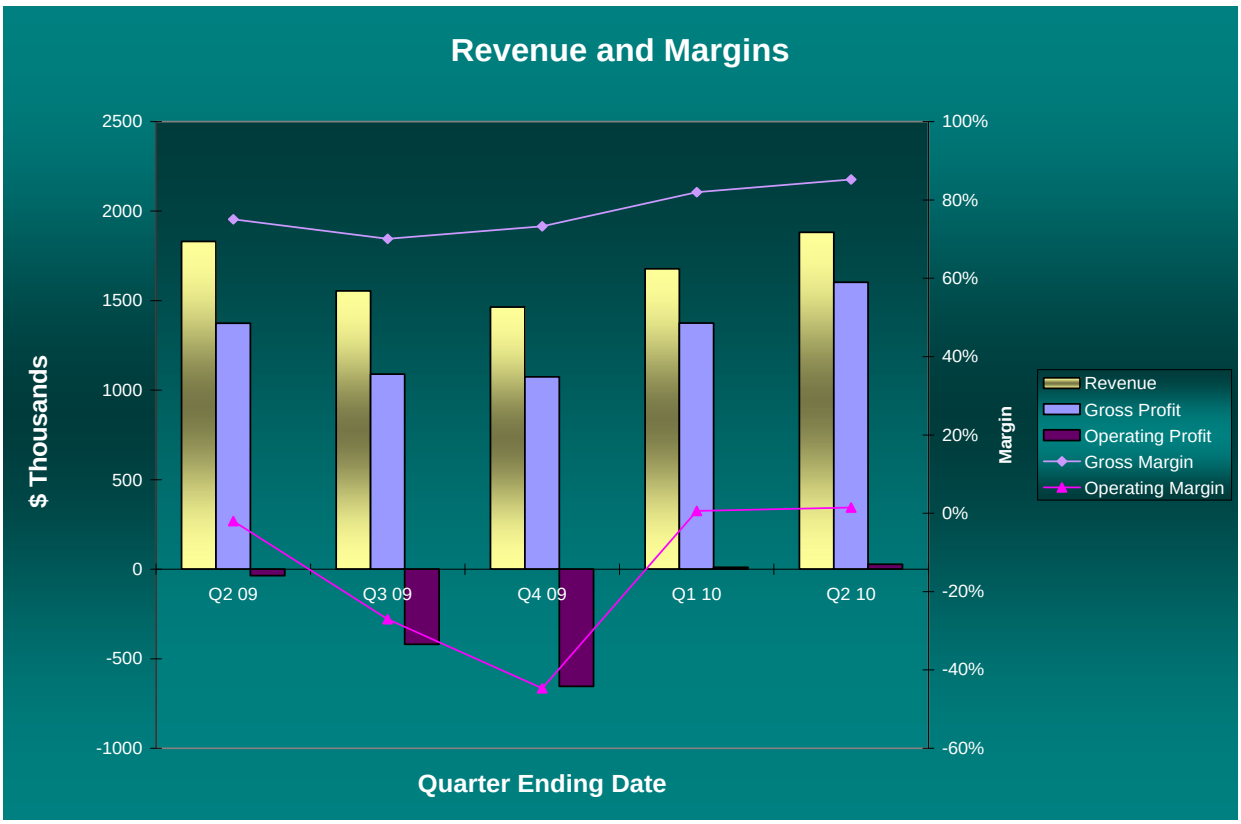
DATATRAK competes in this market on the strength of its software's functionality, design architecture and data entry and review tools. The firm believes its greatest strength is directly related to its offering of a broad information platform that can be used throughout an organization to efficiently manage its clinical trials. The firm's goal is becoming the "Desktop" for the clinical trials industry.

The Company's competition is paper as well as other technology solutions. The electronic clinical trials technology market is highly competitive and fragmented. The largest competitor is the traditional paper-based method of collecting clinical trial data. In addition, technology applications in this and every industry are always emerging and are characterized by rapid evolutions. At times, the Company also competes with both internal initiatives at its customers as well as those in the CRO industry.

## RECENT NEWS

On August 11th 2010 DATA announced results for the second quarter of fiscal year 2010 ending June 2010. Revenue 2010 increased to $1,881,000 compared to $1,831,000 in the same period of 2009. Gross profit margin improved to 85% compared to 75% for the three months ended June 30, 2009. The improvement in the Company's gross margin reflects a 39% reduction in direct costs.

As of June 30th 2010 cash stood at $924,000, an increase over the March 31, 2010 cash balance of $811,000 – the Company's first positive cash flow from operations since 2006.




On August 2, 2010 DATATRAK International, Inc. announced that DAIICHI SANKYO EUROPE GmbH selected DATATRAK's eClinical platform for a cardiovascular clinical study encompassing 80 sites and 1,200 patients across Europe. DAIICHI SANKYO EUROPE GmbH will utilize DATATRAK's Electronic Data Capture solution in addition to web-based Patient Randomization, Drug Inventory Management, Lab Import and Auto-Coding Engine solutions. Also, study users will be able to view, manage and report on patient data via DATATRAK's dynamic, ad-hoc reporting module. As with all studies for this sponsor, DATATRAK will be producing CDISC SDTM compliant exports throughout the study.

## VALUATION

The firm has four characteristics that should enable it to outperform the industry and the competition.

- Superior Technology
- A Debt Free Balance Sheet
- Growing Backlog
- Increasing Market Share in a Growing Complex Industry.

As complexity and regulatory challenges ration up in clinical trials, paper based methods as well as integrated systems will prove more expensive and less reliable. Investors that buy the stock today they are essentially buying a firm that emerged from the recession of 2008/2009 with no debt, has grown its backlog in four straight quarters, and continues to gain traction in clinical research.

DATA is trading at a reasonable Enterprise Value to Revenue ratio of 1.9x compared to the Software Industry average of 2.2 to 2.3x. Enterprise Value is essentially the takeover price of the company by adding market capitalization, debt, preferred shares etc. and subtracting cash on the balance sheet. We see further upside for the stock and value the firm at $3.00 based on 5.1x our 2011 revenue estimate. While similar firms in the space (OmniComm Systems Inc., Medidata Solutions Inc.) have lower multiples it should also be noted they have significant debt levels.

| Item | 2008 | 2009 | 2010 |
|---|---|---|---|
| **Backlog:** | Trending Down | Trending Up | Trending Up |
| **Income/ Loss:** | $(17) M | $(1.9) M | 2nd Quarterly Profit |
| **Balance Sheet Debt:** | $3M Note | No Debt | No Debt |
| **Cash Flow:** | $(1.8) M | $(1.4) M | Turned Cash Flow Positive in Q2 |
| **Auditor Opinion:** | Noted $3M Balloon Debt Payment Due | Going Concern | Clean |

## RISKS

- Changes in the regulatory environment could lead to a decrease in the industry's research and development expenditures.

- In the EDC market, the firm must compete with the traditional paper method of collecting clinical trial data,. The major competitors in the EDC market also include in house development teams, EDC software vendors and single component solutions.

## INSIDER TRADING AND OWNERSHIP

Institutional holders hold 8.5% shares out standing. The top four institutional holders are Potomac Capital Management, Inc. (with 8.35% of the total shares outstanding), Pekin Singer Strauss Asset Management Inc. (0.1%), Winslow Asset Management Inc. (0.1%) and Glenmede Trust Co. (0.1%). Two of the top four holders added to their positions in the past quarter, while two reported no change in holdings.

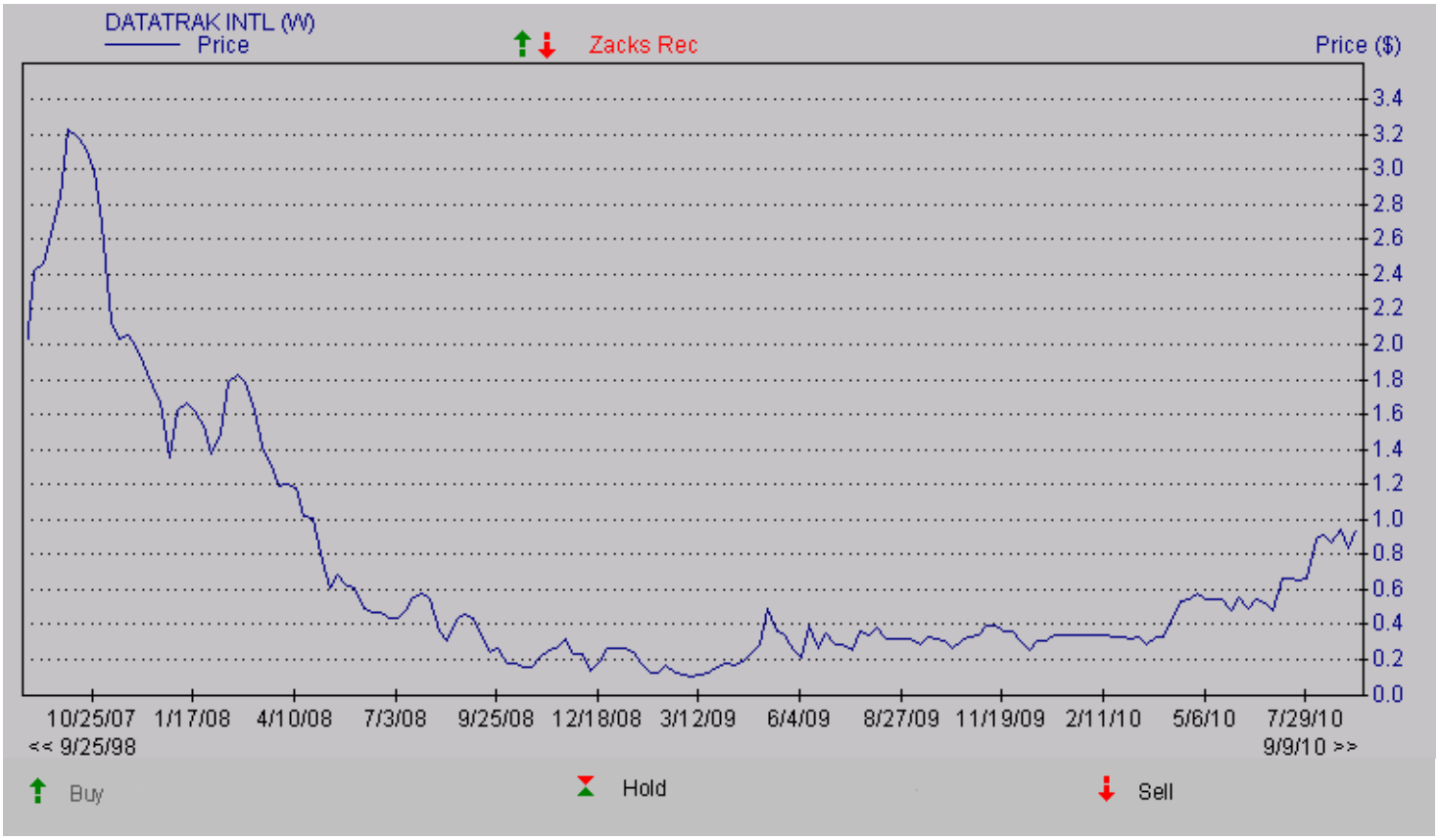
Insiders hold approximately 8% of the firm's shares outstanding. Insiders were net buyers over the last two quarters.

# PROJECTED INCOME STATEMENT & BALANCE SHEET

| INCOME STATEMENT ($ Thousands | Jun-09 Q2 09 | Sep-09 Q3 09 | Dec-09 Q4 09 | Mar-09 Q1 10 | Jun-10 Q2 10 | Sep-10 Q3 10 E | FY 2006 | FY 2007 | FY 2008 | FY 2009 | FY 2010 E | FY 2011 E |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **REVENUE** | | | | | | | | | | | | |
| **Net Revenue** | **1,830.52** | **1,554.13** | **1,464.44** | **1,677.65** | **1,880.57** | **1920.0** | **17,690.00** | **10,562.00** | **8,826.00** | **6,935.27** | **7,470.00** | **8,217.50** |
| *Sequential Growth* | | *-15%* | *-6%* | *15%* | *12%* | *2%* | | | | | | |
| **OPERATING EXPENSES** | | | | | | | | | | | | |
| Cost of Revenues | 457.02 | 464.79 | 391.10 | 302.71 | 277.60 | 279.50 | 5,222.00 | 4,583.00 | 2,833.00 | 1,786.78 | 1,141.81 | 1238.9 |
| *% of Revenue* | *25.0%* | *29.9%* | *26.7%* | *18.0%* | *14.8%* | *14.6%* | | | | | | |
| **Gross Profit -** | **1,373.49** | **1089.3** | **1,073.34** | **1,374.94** | **1,602.97** | **1640.5** | **12,468.00** | **5,979.00** | **5,993.00** | **5,148.49** | **6328.2** | **6978.6** |
| *Proforma Gross Margin* | *75.0%* | *70.1%* | *73.3%* | *82.0%* | *85.2%* | *85.4%* | *70.5%* | *56.6%* | *67.9%* | *74.2%* | *84.7%* | *84.9%* |
| R&D + Engg | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| *% of Revenue* | *6.7%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* |
| SG&A | 1,422.23 | 1,425.93 | 1,614.30 | 1,491.50 | 1,530.41 | 1532.50 | 13,266.00 | 13,097.00 | 10,179.00 | 6,106.03 | 6,094.00 | 6,250.00 |
| *% of Revenue* | *77.7%* | *91.8%* | *110.2%* | *88.9%* | *81.4%* | *79.8%* | *75.0%* | *124.0%* | *115.3%* | *88.0%* | *81.6%* | *76.1%* |
| GW Amort, Restructuring, other | *(12.55)* | *83.78* | *113.58* | *(127.11)* | *45.26* | *40.00* | *2,601.00* | 3,850.0 | *15,287.0* | 940.4 | *(0.03)* | *(0.05)* |
| *% of Revenue* | | | | | | | | | | | | |
| Total Operating Expenses | 1409.68 | 1,509.71 | 1,727.88 | 1,364.40 | 1575.67 | 1572.50 | 15,867.00 | 16,947.00 | 25,466.00 | 7,046.44 | 6,093.97 | 6,249.95 |
| *% of Revenue* | *77.0%* | *97.1%* | *118.0%* | *81.3%* | *83.8%* | *81.9%* | *89.7%* | *160.5%* | *288.5%* | *101.6%* | *82%* | *76%* |
| **Operating Income -** | **-36.18** | **-420.37** | **-654.53** | **10.55** | **27.30** | **68.0** | **(3,399.00)** | **(10,968.00)** | **(19,473.00)** | **(1,897.95)** | **234** | **729** |
| *Operating Margin* | *-2.0%* | *-27.0%* | *-44.7%* | *0.6%* | *1.5%* | *3.5%* | *-19%* | *-104%* | *-221%* | *-27%* | *3%* | *9%* |
| **NON-OPERATING ITEMS** | | | | | | | | | | | | |
| Non operating Income/Expense | -2.7 | -3.5 | -2.7 | -1.2 | -2.6 | -3 | -115.0 | 68.0 | 3,061.00 | -9.9 | -6 | -5 |
| *% of Revenue* | *-0.15%* | *-0.22%* | *-0.19%* | *-0.07%* | *-0.14%* | *-0.14%* | *-0.65%* | *0.64%* | *34.68%* | *-0.14%* | *-0.08%* | *-0.06%* |
| Tax Provision | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 976.00 | -46.00 | 385.00 | 0.0 | 0 | 0 |
| *Effective Tax Rate* | | | | | | | | | | | | |
| **Net Income -** | **-38.85** | **-423.86** | **-657.27** | **9.38** | **24.67** | **65.25** | **(4,490.00)** | **(10,854.00)** | **(16,797.00)** | **(1,907.85)** | **228.2** | **723.7** |
| *Net Income Margin* | *-2.1%* | *-27.3%* | *-44.9%* | *0.6%* | *1.3%* | *3.4%* | *-25.4%* | *-102.8%* | *-190.3%* | *-27.5%* | *3%* | *9%* |
| **EARNINGS PER SHARE** | | | | | | | | | | | | |
| **EPS - Basic** | $0.00 | -$0.03 | -$0.05 | $0.00 | $0.00 | $0.00 | -$0.40 | -$0.82 | -$1.23 | -$0.14 | $0.01 | $0.04 |
| EPS - Diluted | $0.00 | -$0.03 | -$0.05 | $0.00 | $0.00 | $0.00 | -$0.40 | -$0.82 | -$1.23 | -$0.14 | $0.01 | $0.04 |

Ken Nagy, CFA Zacks Investment Research 9/13/2010

## HISTORICAL ZACKS RECOMMENDATIONS




## DISCLOSURES

**The analysts contributing to this report do not hold any shares of DATA. Zacks EPS and revenue forecasts are not consensus forecasts.** Additionally, the analysts contributing to this report certify that the views expressed herein accurately reflect the analysts' personal views as to the subject securities and issuers. Zacks certifies that no part of the analysts' compensation was, is, or will be, directly or indirectly, related to the specific recommendation or views expressed by the analyst in the report. Additional information on the securities mentioned in this report is available upon request. This report is based on data obtained from sources we believe to be reliable, but is not guaranteed as to accuracy and does not purport to be complete. Because of individual objectives, the report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed herein are subject to change. This report is not to be construed as an offer or the solicitation of an offer to buy or sell the securities herein mentioned. Zacks or its officers, employees or customers may have a position long or short in the securities mentioned and buy or sell the securities from time to time. Zacks uses the following rating system for the securities it covers. **Outperform**- Zacks expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters. **Neutral**- Zacks expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters. **Underperform**- Zacks expects the company will under perform the broader U.S. Equity market over the next one to two quarters. The current distribution of Zacks Ratings is as follows on the 1004 companies covered: Outperform- 13.8%, Neutral- 79.4%, Underperform – 6.4%. Data is as of midnight on the business day immediately prior to this publication.