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A Novel Way to Invest in Biopharma - QuintilesIMS

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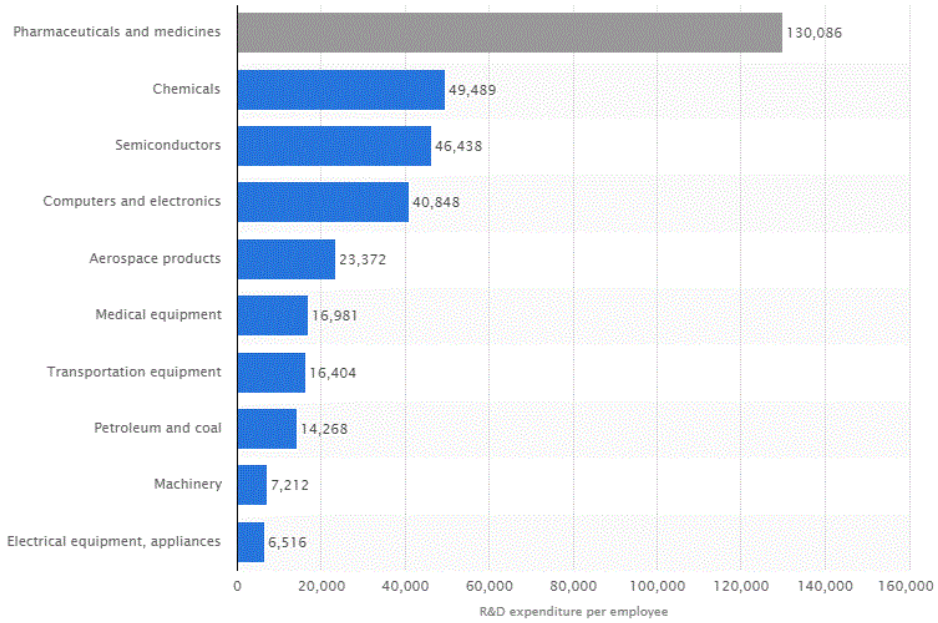
Between October of 2010 and February of 2011, the FDA rejected three potentially ground-breaking obesity drugs after major phase III clinical trials. Despite the fact that over 33 percent of Americans were obese at the time, there were no significant drug therapies for obesity. Along with the weight issue comes diabetes, cardiovascular issues, and a host of other collateral damage to the body. The first company to face the FDA guillotine was San Diego based Arena pharmaceuticals. They conducted huge phase I, II, and III trials, involving 8,963 patients at a cost of more than $400 million. The FDA was concerned about its obesity drug, Lorqess, because it caused cancer in rats although there were no such indications in the large clinical trials in humans. In February of 2011, Lorqess was rejected by the FDA. Arena's stock price dropped 80 percent. Other obesity drugs such as Orexigen's Conrave and Vivus' Qnexa met similar fates, although for different reasons. It had been over a decade since the regulatory body approved any weight loss drug. Despite having enrolled 18,000 patients at a cost nearing a billion dollars, the three companies had no drug to show for all the years of effort and money invested. Fortunately congress became involved in the FDA's draconian rejection record and began to pressure the administration in an attempt to moderate the massive failure rate of drug approval. These drugs were approved within a few years after the FDA reconsidered new data.

One extreme example of the costs of drug development involves the costs of clinical trials for J&J's Xarelto and Bristol Myers' (and Pfizer's) Eliquis. Costs exceeded $6 billion dollars and the companies enrolled a mind-boggling 130,000 patients for the stage III trials for the the factor Xa Inhibitor that is used to treat cardiovascular diseases such as Atrial Fibrillation and Venous Thrombosis. (See figure 1 to see just how much more the Biopharmaceutical sector spends than other sectors of the economy.) *Source: Avi Roy, Manhatten Institute.*

The cost of drug development in the United States has continually escalated and stands in the billions depending on whose research you read. A good deal of the cost is locked up in navigating the various clinical trials required by the United States Food and Drug Administration (FDA)—especially the phase III trials which, on average, are about 90-95 percent of the total costs of the three phases. Approval can mean large profits for the successful company; rejection spells a huge loss of money and adverse consequences for any publicly traded company. Just ask Eli Lilly. *After announcing in November the failure of their promising Alzheimer's* drug, Solanezumab, in stage III trials, the stock price fell off the cliff. Despite Lilly's financial strength and a long successful operating history, Lilly's shares dropped over 10% on the news. In view of these examples and the vast need for newer drugs and therapies to combat an aging society, pharmaceutical companies must respond to the escalating complexity and costs involved in drug development.

Figure 1: R&D Expenditures per Employee by manufacturing Subsector/industry 2000 – 2010



Source: Statista

Clinical trials take years, require huge investment costs, and their increasing complexity make it difficult for even the strongest companies to move forward. Xarelto had over 60,000 patients enrolled in their stage III trial. Imagine the massive record keeping and data generated by 60,000 patients over the life of a clinical trial… all the blood tests… all the physician/nursing reports… as well as the other exams and procedures. The trend over the years makes these trials even more complex and capital intensive, as the average length of a trial has increased from 500 days to nearly 800, and the number and types of routine blood tests, x-rays and other exams has grown significantly. Understandably, pharmaceutical companies, more than ever, are outsourcing some of their complex clinical trials to Contract Research Organizations (CROs) as they seek more efficient clinical trials and ways to increase their odds of success at recouping their investment and subsequently making a profit. To achieve these goals the biopharmaceutical industry will often partner with CROs. We begin 2017 investigating one the best in the business—QuintilesIMS (Ticker symbol Q).

Since the launch of the clinicaltrials.gov database site in 2000, approximately 230,000 clinical trials have been registered. 24,000 of these trials were conducted in 2016.

–Credit Suisse Equity Research (Dec 2016)

"New therapies are needed to treat not only common conditions such as cardiovascular disease, cancer and Alzheimer's disease, but also diseases that we either thought were cured, like drug-resistant bacterial infections or tuberculosis; diseases we did not previously recognize, such as the potential link between in utero Zika infection and microcephaly; or curiosities from medical textbooks, such as Ebola and dengue fever."

–Tom Pike,
CEO QuintilesIMS

QuintilesIMS is really two unique companies in one. In fact, Quintiles Transnational and IMS Health merged in 2016 to form the combined entity. The merger was completed in October of 2016. I have long been a fan of IMS Health before it was folded into Quintiles. For the purposes of this issue, we will cover their basic businesses separately, but we will present the financials and investment thesis as one consolidated entity. QuntilesIMS indeed has a strange name. They haven't invented any miracle drugs to cure or treat disease such as Vertex's Kalydeco or other biopharma blockbusters, but you can be sure that odds are good, most of the drugs we are familiar with went through a clinical trial that QuintilesIMS had a hand in organizing. Their products and services are a vital prerequisite for the pharmaceutical industry as it takes a drug from the research lab, to FDA approval, to the shelves of a pharmacy. They also have a huge arm (the former IMS division) that possesses critical data on the prescribing habits of doctors, as well as a massive database on prescription drugs filled at major pharmacies like CVS and Walgreens. Even if the drug fails in late stage trials, QuintilesIMS still gets paid. Could it be the biopharm equivalent of a picks-and-shovels company?

The California Gold Rush began in early 1848, and the number of people flocking to the state was no surprise as "thar was gold in them hills." All told, the news of gold brought some 300,000 people to California from the rest of the United States and abroad. The Gold Rush was on… But what most people failed to see as this legendary story goes, is that the real wealth was not made by those digging holes all over Cali looking for gold deposits. The real money was made by those selling pickaxes, shovels and other mining equipment and services to overly-enthusiastic miners. True, some made fortunes finding gold in the ground; but far more struck out and were left holding the proverbial bag (of picks and shovels).

Source: USPS

*QuintilesIMS is, in a strange sort of way, a picks-and-shovels company. For every blockbuste*r like Humira or Lipitor, drug companies will suffer many failures in their search for the next breakthrough medicine. Q helps drug companies plan and orchestrate the all-important, late-stage clinical trials. Since the 1940s when antibiotics were used to combat Tuberculosis, clinical trials have been crucial in demonstrating the safety and effectiveness of the drugs used in modern medicine.

CROs (Quintiles is the largest) advise and consult with clients about every aspect of these important FDA trials. They plan and organize the trials, as well as dealing with the submission for regulatory approval. If you want an up-close and personal look at an FDA new drug application, check out the book The Antidote by Barry Werth. Werth wrote about Vertex pharmaceuticals and was given unlimited access to the company's senior management and scientists. He had a CEO's view into Vertex's NDA (new drug application) submission for Teleprevir, the Hep-C drug they brought to market after a 15-year effort. Over a million pages were submitted as part of the regulatory approval process. Quintiles' expertise, infrastructure and massive database on clinical trials make them the go-to company for nearly every major pharmaceutical firm in the United States (See figure 2).

Figure 2: How QuintilesIMS adds value to Biopharm's critical clinical trial requirements.

Source: ISAW research

Where Q really can add value is in achieving efficiencies that speed clinical trials along at a faster rate. As an illustration, let's examine the immuno-oncology drug Keytruda, Merck's blockbuster PD-1 inhibitor that is gaining wide acceptance in multiple cancer indications. What if, due to efficient design, the stage III trials were accelerated to completion 3 months ahead of schedule, and FDA approval was gained a quarter or two early? Given that Keytruda will be a multibillion-dollar blockbuster, the revenues gained to Merck, from the earlier approval, can be substantial and into the tens of millions. Now, we're not saying Keytruda's trials were completed early, or even that QuintilesIMS had a hand in Keytruda's trials; we are merely trying to illustrate the benefits that Quintiles might add to trial outcomes. It should come as no surprise that clinical trial sponsors (drug companies) are willing to pay a premium for this service since it would pay for itself.

The IMS part of QuintilesIMS is also an attractive business, one I came close to purchasing many years ago but couldn't because the company was taken private by TPG and Canada Pension Plan Investment Board (the largest pension plan in Canada).

Today, most people would agree that information is a valuable commodity. Simply survey the success of Google and Facebook at monetizing the information they have – both firms make tens of billions in advertising because they have access to vast storehouses of information and attract billions of users to the search firm and the social networking giant.

While IMS isn't quite the same business model as a Google or Facebook, they have a compelling story:

- IMS' database contains over 15 petabytes of information. To give this scale, 1 petabyte is equal to 20,000,000 four-drawer filing cabinets, filled with text; 1.5 petabytes = the size of 10 billion photos on Facebook; 50 petabytes = the entire written works of mankind since the beginning of history in all languages. Clearly, IMS has a very big database.
- IMS processes over 45 billion healthcare transactions per year (that's 6 for every man, woman and child on the planet).
- IMS collects data from 780,000 streams of Data and organizes them into comprehensive databases.
- IMS has 500 million longitudinal studies and anonymous patient records. (Longitudinal studies are those done on the same patients over a long period of time.) The famous Framingham Heart Study is an example of a longitudinal study. Patients were studied regularly over decades and had thorough evaluations to determine cardiovascular health. The results of the study laid the groundwork for determining who is at greater risk for a cardiovascular incident (heart attacks…etc.). The result was major advances in treating heart disease and greater survival for those who suffered heart attacks. IMS has half a billion of these types of studies (although likely not as large and encompassing as the Framingham Study).

Imagine if you had access to information regarding a substantial percentage of the prescription drug sales in the United States. What if you knew the pharmacy, the doctor prescribing the medicine, and you had reams of data about the patient as well, with the exception that all the data was "anonymized" (i.e. names removed from the database so that patients' confidentiality is preserved.) Furthermore, what if you had the information on medical records…blood tests…procedures…diagnosis…etc.…on millions of "anonymized" individuals? IMS Health (as it was known before their merger with Quintiles), has substantial amounts of this data.

So how is this data useful to big pharma? Let's consider a doctor, a group of doctors, or even a hospital prescribing Prozac (made by Eli Lilly), more often than Zoloft (made by Pfizer). Pfizer would be a likely subscriber to IMS' database and would know who in the country is prescribing the competitor drug, Prozac, over its Zoloft drug. With this information, Pfizer could allocate teams of pharma reps to that area or more specifically the doctors. The hope would be, to convince some of these professionals to switch to the Pfizer product.

Clearly the expertise and databases that both entities possess is valuable. When the two companies merged late in 2016, a juggernaut of healthcare information and IT was formed. QuintilesIMS has thousands of large customers in the pharmaceutical business and in the healthcare space. The firm boasts a client retention rate of nearly 100 percent among its largest customers—unheard of in most businesses. Another key attribute to this firm: The average length of QuintilesIMS' relationship with their top customers is on the order of 25 years. How many firms in the ultra-competitive business world stick with a service provider for that length of time? It speaks volumes to the quality of their work and the reputation of the company, if not also to the lifecycle of Pharma's R&D pipeline and on-going drug trials.

Investment Thesis—QuintilesIMS

- Q doesn't easily lend itself to the typical analysis at this point, because of the recent merger. Debt levels have soared in order to finance acquisitions. In time, the numbers will consolidate, the debt will be reduced, and shareholder equity will rebuild. Still, the metrics we can see are solid. The P/E ratio is reasonable at about 20. Its relative P/E ratio is slightly above 1 and stands at 1.05. Not too expensive…but not cheap either (see figure 3 above)
- Return on invested capital is a solid 17.5%. Return on Equities are not applicable because equity is temporarily in deficit. Remember, this is a company that has massive databases and expertise. It doesn't have significant tangible assets like real estate, buildings or a portfolio of investments.
- Earnings and revenue forecasts are solid and well into double digits. Valuation metrics such as Price to sales and Price to free cash flow are also reasonable like the P/E ratio.
- One of QuintilesIMS' biggest strengths rests with a very large and growing backlog of orders. The book to bill ratio (business booked / actual revenues) is a healthy 1.23.
- I like that officers and directors (company insiders) own over 10 percent of the shares outstanding. They have skin in the game and we always like to see shareholder and management goals aligned.

Figure 3: QuintilesIMS Metrics

Ticker Symbol	Q
Market Capitalization	$19.5 billion
Long term debt	$2.4 billion
Price Earnings Ratio current	19.4x
Relative P.E. Ratio	1.05
Dividend yield	0.0%
Operating Margin (2017 est)	23.0
Return on Invested Capital	17.5%
Est 5-year Earnings growth	12.0%
Past 5-year Earning growth	17.8%
Price to Free Cash Flow	18.2x
Price to Sales	1.6x
Price to Earnings growth	1.3x
1-year Total Return	12.7%
3-year Total Return	70.9%
Does business in	Over 100 countries
Insiders own:	10.9% of shares
Order backlog 2011	$7.9 billion
Order backlog 2015	$12.1 billion
Book to Bill Ratio	1.23 (new business/revenues)

Source: Bloomberg, Morningstar, ISAW Research

Risks to the Business

- The entire CRO business is vulnerable to changes in spending for drug development and R&D. While trends look positive for companies to outsource their clinical trials, any reduction in capital spending or budgets for R&D could have an adverse impact on revenues on QuintilesIMS and their competitors.
- With its large size, if they were to lose a clinical trial client, they would survive. No one client makes up more than 10% of revenues; the impact would be minimal.
- Although IMS' vast archive of data and medical records are "anonymized" for privacy concerns, there is a growing concern that patients will demand increased privacy going forward. In fact, several court cases have been tried against the IMS entity, but all have lost. However, should the courts prove friendlier to privacy concerns, additional litigation could be brought, and that poses a risk to IMS massive data-gathering potential in the future. Should patients be allowed to opt out of having data collected, this will cause headaches for QuintilesIMS.

Final thoughts

This is a solid company that rides the coattails of drug development and commercialization. As biopharmaceutical companies shuttle potential drugs from initial concept to placement on pharmacy shelves, there are hundreds of questions that must be answered. QuintilesIMS helps the pharmaceutical industry arrive at solutions. Their massive scale and reputation in the industry is second to none. While Quintiles does have several competitors, they are in a solid position and should be able to grow their business substantially. The stock has traded as high as $81.4 a share. In 2013 they traded at $40 a share. They have had a nice ride higher. The merger does present investors with some questions: Will Q be able to realize those all-important merger related synergies in the months/years ahead? Will the merger proceed smoothly and will these two newly-weds grow their marriage? Personally, I have liked IMS for years. I find it an attractive company and a play on the biotechnology/pharmaceutical sector. It currently trades around $76 a share. I would like to see it 5-10 percent lower—and plan on picking up shares in the low $70 per share range.

Recent Purchases

When Jodie and I first conceived the idea of starting *In Sickness and Wealth*, I expressed two concerns: The first was the lack of time in our schedules given each of our responsibilities and our "day jobs." The second was that the healthcare sector basically had several decades of outperforming the market in general, and that one day, the sector would experience a year or so of low or even negative performance. We figured out a way around the time issue (we love working 80 hours a week!!), but the second worry did come to pass. While the Dow and the SP 500 were up nicely in 2016, the healthcare sector as measured by the S&P 500 Select Sector healthcare ETF (XLV) was down over 5 percent. While the personal portfolio held up nicely (stocks held for all of 2016 were up more than 10 percent due to large holdings in JNJ, Stryker and Becton Dickinson, which did very well), some issues in healthcare took a dive. Two of our holdings, Illumina and Express Scripts are on close watch and have disappointing performance (I sold calls on ESRX long ago, before we started this publication, so the damage has been mitigated). I would love to hold on to them, despite their disappointing performance over the last several quarters, but they will be on a short leash. Good risk management is the crux of good investing.

On the other hand, we mentioned in several issues, and in recent blog posts, that we would use any decline in the sector to initiate positions in stocks we find attractive. Last month we did some fishing…

- **Novo Nordisk (NVO)**—the premier company in the diabetes space. With formulary issues with Express Scripts, the general drag on healthcare stocks, and the scare that the ACA would be repealed (not to mention some lower guidance for 2017), Novo had a severe decline from $57 a share down to nearly $30—a 47% drop in less than six months. With its nearly 50% market share in diabetes medication, we figured the shares represent a good risk reward in the 30s and picked some shares up around $35.75. Stay tuned.
- **McKesson (MCK)**—a price war, a slow-down in generic drug usage, and some negative guidance from McKesson, cut it nearly in half from the $240 area all the way down to a $114 per share (intra-day low on the day of the guidance announcement). It has since bounced back to the $140 area. We added a very small position at $143.52. While we are long-term investors, if McKesson should break that $114 intraday support level, we would consider selling, as it would indicate the business model has been adversely impacted. McKesson is a blue chip and thus rock-solid. But its low net margins would be at risk if the pharma supply chain is undergoing a major transition into slower growth. Needless to say, we will be watching this one closely.

- **Walgreens Boots Alliance (WBA)**—while I am not a fan of retailing, I do like both Walgreens and CVS. We did some put writing on Walgreens and sold the April 2017 82.50 strike puts for $3.20 ($320 of premium). The $320 is ours to keep no matter where Walgreens trades in April of 2017. We win several ways with this. If Walgreens advances and stays above 82.50 by April, we keep the premium. If Walgreens is at $82.50 at expiration, we keep the premium. If Walgreens is below $82.50 at expiration, we keep the $320 and 100 shares of Walgreens will be put into the personal portfolio account at the strike price–$82.50. Owning the stock at $82.50 per share plus the $320 kept from selling the put, gives us an "effective purchase price" of $79.30. This strategy gives us a little income – sort of an extra dividend – and forces us to buy WBA a few points lower, should it drop. If WBA is below that effective purchase price (aka, breakeven price), we will have a loss. If WBA sinks dramatically below $79.30, we will have large losses. And if Walgreens has a catastrophic decline—say 50 percent (highly unlikely) – and the stock goes to $40 a share, we will own a stock at $79.30 that is trading at $40… do the math. Put selling is not for everyone. Make sure you work with a financial advisor who is experienced in selling options. And make sure you have a large enough account to do put selling strategies. Most brokerage firms will not let you sell options unless you meet certain financial requirements.

In Sickness and Wealth strongly urges readers to do their homework and have some experience with options before selling them as in this case. For those with no experience, losses can be very large. I have been doing options writing for 30 years so I am familiar with the risks. Sellers…BEWARE.

Dave Lerman / Jodie Warner