Zacks Small-Cap Research

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# Cryoport Inc (CYRX-NASDAQ)

## *CYRX: FDA Advisory Panel Recommends Approval of CTL019. Increasing PT To $8/Share*

Average comparable PE/G (excluding high and low outliers) is 1.81 which is applied to our forecasted revenue growth rate of CYRX of 51% through fiscal 2021. The result, $11.5/share, is discounted back to the present at a CAPM-calculated discount rate of 13.1% to come to present value of approximately $8/share.

| | |
|---|---|
| Current Price (07/19/17) | $5.72 |
| **Valuation** | **$8.00** |

## OUTLOOK

Last week an FDA advisory panel voted unanimously (10-0) to approve CTL019 (tisagenlecleucel-T), a novel CAR-T cell immunotherapy developed by Novartis. As a reminder, CYRX recently revealed that they have been chosen to support the commercialization of CTL019. Despite an adverse event profile that includes certain and potentially serious risks, such as cytokine release syndrome (i.e. extreme inflammatory reaction), given the extraordinary clinical data and unanimous vote in favor of approval by the FDA panel, we think U.S. regulatory approval (by October) is all but guaranteed. And despite the relatively small initial market size for CTL019, the results of the panel review did positively effect our model. While we had previously handicapped eventual FDA approval (mostly due to the side effect profile), we now incorporate 100% chance of U.S. regulatory approval given the unanimous vote by the expert panel in favor of the same. This resulted an incremental increase in expected revenue in the amounts of $500k in fiscal 2018, $1M in 2019 and $1.5M in 2020. The update to our model contributed (along with an increase in comp valuations) to our CYRX per-share price target moving from $6 to $8.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$6.16** |
| **52-Week Low** | **$1.63** |
| **One-Year Return (%)** | **218.54** |
| **Beta** | **0.54** |
| **Average Daily Volume (sh)** | **117,894** |
| **Shares Outstanding (mil)** | **24** |
| **Market Capitalization ($mil)** | **$137** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **9** |
| **Insider Ownership (%)** | **13** |
| **Annual Cash Dividend** | **$0.00** |
| **Dividend Yield (%)** | **0.00** |
| **5-Yr. Historical Growth Rates** | |
| **Sales (%)** | **71.5** |
| **Earnings Per Share (%)** | **N/A** |
| **Dividend (%)** | **N/A** |
| **P/E using TTM EPS** | **N/A** |
| **P/E using 2017 Estimate** | **N/A** |
| **P/E using 2018 Estimate** | **N/A** |
| **Zacks Rank** | **N/A** |

| | |
|---|---|
| **Risk Level** | **High,** |
| **Type of Stock** | **Small-Growth** |
| **Industry** | **Shipping** |

## ZACKS ESTIMATES

**Revenue**
(in '000s of $)

| | Q1 (Mar) | Q2 (June) | Q3 (Sep) | Q4 (Dec) | Year (Mar) |
|---|---|---|---|---|---|
| 2016 | 1556 A | 1918 A | 1977 A | 2229 A | 7,679 A |
| 2017 | 2712 A | 2877 E | 3186 E | 3591 E | 12,366 E |
| 2018 | | | | | 20,479 E |
| 2019 | | | | | 30,098 E |

**Earnings per Share**

| | Q1 (June) | Q2 (Sep) | Q3 (Dec) | Q4 (Mar) | Year (Mar) |
|---|---|---|---|---|---|
| 2016 | -$0.26 A | -$0.28 A | -$0.14 A | -$0.25 A | -$0.93 A |
| 2017 | -$0.10 A | -$0.08 E | -$0.09 E | -$0.08 E | -$0.35 E |
| 2018 | | | | | -$0.26 E |
| 2019 | | | | | -$0.18 E |

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

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**Expect FDA Approval of NVS' CTL019, Prompts Upward Revenue Revisions To Our Model/PT**
Last week an FDA advisory panel voted unanimously (10-0) to approve CTL019 (tisagenlecleucel-T), a novel CAR-T cell immunotherapy developed by Novartis, for the treatment of children and young adults (ages 3 - 25) with relapsed or refractory B-cell acute lymphoblastic leukemia (ALL). B-cell ALL is a form of Leukemia (i.e. blood cancer) in which lymphoblasts (i.e. immature white blood cells) are overproduced in the bone marrow, resulting in the production of abnormal (cancerous) blood cells and inhibiting the production of other, healthy cells.

As a reminder, CYRX recently revealed that they have been chosen to support the commercialization of CTL019. CTL019 therapy requires blood cells to be extracted from the patient, cryopreserved and shipped to Novartis' laboratories where they are re-engineered. The cells are then refrozen and shipped back to the treating physician. These complex processes can create logistical challenges and, coupled with critical importance of maintaining the integrity of the cells at all times, are some of the reasons why we believe NVS has teamed up with CYRX. While CryoPort has not publicly disclosed their specific role, given their wheelhouse is cryopreserved shipping, logistics and payload monitoring, we think it reasonable to assume they will have direct involvement with CTL019 in all of these functions.

Annual U.S. incidence of B-cell ALL is estimated at approximately 6k cases, roughly 60% of which are under the age of 20. Prevalence in the U.S. is believed to be about 30k. While the 5-year survival rate of B-cell ALL patients, at approximately 85%, is relatively high, that is not the case for those patients that are refractory (i.e. resistant) or have relapsed from treatment. In these r/r patients, 5-year survival falls to just 16% - 30%. In NVS' pivotal study, 83% of r/r B-cell ALL patients achieved remission at 90 days and remained cancer-free at six months. In addition, the probability of being relapse-free was 75% at six months and 64% at 12 months among those patients that responded. Finally, the probability of survival was 89% at six months and 79% at 12 months. The results are considered remarkable and potentially revolutionary in terms of progress towards an eventual cure for cancer.

CTL019 has breakthrough status from the FDA for this r/r B-cell ALL indication. Despite an adverse event profile that includes certain and potentially serious risks, such as cytokine release syndrome (i.e. extreme inflammatory reaction), given the extraordinary clinical data and unanimous vote in favor of approval by the FDA panel, we think U.S. regulatory approval of CTL019 is all but guaranteed. As a reminder, CYRX expects, logistics and shipping support for a commercialized product could be worth between $2M and $20M in revenue to the company.

But the relatively small size of the r/r B-cell ALL market - which we estimate at ~1k patients in the U.S. (and, perhaps another 1k in Europe), means it may not represent an overly significant initial opportunity for CYRX in terms of revenue. That said, given that rumored potential per-treatment pricing of CTL019 is as high as $600k (or more) and expectations that it reaches blockbuster status ($1B+ annual sales), there should be no lack of financial resources to support the critical cryopreservation, shipping and logistics functions.

And despite the relatively small market size, the results of the panel review did positively effect our model. While we had previously handicapped eventual FDA approval (mostly due to the side effect profile), we now incorporate 100% chance of U.S. regulatory approval given the unanimous vote by the expert panel in favor of the same. This resulted an incremental increase in expected revenue in the amounts of $500k in fiscal 2018, $1M in 2019 and $1.5M in 2020. The update to our model contributed (along with an increase in comp valuations) to our CYRX per-share price target moving from $6 to $8.

***CTL019 Label Expansion Could Offer Additional Upside***…
NVS hopes to expand the CTL019 label to include the treatment of other cancers including relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL), for which it has also received breakthrough therapy status by the FDA. Interim results of their phase II study, announced in early June 2017, were positive. NVS hopes to file for approval in both the U.S. and Europe for the treatment of r/r DLBCL. Approximately 20k Americans are diagnosed with DLBCL each year, of which about 7k will either not respond to initial treatment or will relapse. As such, and estimating the European market represents another ~7k potential patients, an r/r DLBCL indication could more than triple CYRX's relative opportunity as it relates to CTL019.

And additional indications related to CTL019 could follow. Additionally, NVS has other CAR-T cell programs ongoing which, presumably, CYRX could also eventually be engaged in supporting. This includes CTL119 for r/r chronic lymphocytic leukemia - in late May NVS announced positive results of a pilot study of CTL119 in combination with ibrutinib.

***Supporting CTL019 Provide Compelling Marketing Message for CYRX…***

The other likely, and perhaps even more valuable, benefit of providing support of CTL019 is the awareness and validation that that it provides to CYRX as the leader in cryopreservation/logistics/transport/chain-of-custody of cell-based therapies. One of the challenges with immunotherapies is minimizing the amount of time that it takes to transport (and all the functions that are involved in that) the cells from the patient to the lab and back to the patient again. Time is of the essence as; these are very sick patients in most cases and time is the enemy of cell viability.

The positive expert FDA advisory panel recommendations and comments relative to the extraordinary efficacy of CTL019 - which included a comment by one panel member that it was the most exciting thing he had seen in his career - received widespread news coverage. FDA approval and launch is almost certain to elicit another wave of mass-publicity and enthusiasm. We believe that this early publicity and clinical success of CTL019 may provide CYRX with perhaps their single-most significant marketing message as it relates to customers entrusting them with these cryopreservation/logistics/transport/chain-of-custody functions that are so critical in the therapeutic supply chain. Given the recent and growing massive inflow of investment dollars targeting immunotherapy development, we think CYRX's commercialized support of CTL019 (and possibly Kite's KTE-C19 as well) could represent the beginning of the next inflection in demand growth for CYRX's services.

**Kite's KTE-C19 Could Be Next**

CYRX is also supporting Kite Pharma's KTE-C19 (axicabtagene ciloleucel) candidate, a chimeric antigen receptor developed to treat aggressive non-Hodgkin lymphoma. In December 2015 axicabtagene ciloleucel received Breakthrough designation by FDA for DLBCL, transformed follicular lymphoma (TFL) and primary mediastinal B-cell lymphoma (PMBCL). In February 2017 they announced positive data from their pivotal study (dubbed ZUMA-1), which is supporting the BLA filing for r/r non-Hodgkin lymphoma. Kite completed their BLA submission to FDA at the end of March 2017, which was subsequently granted priority review by FDA with a PDUFA date of November 29, 2017 - approximately two months after that of NVS's for CTL019. Kite expects to submit for European regulatory approval as well.

Kite also recently announced positive data from a Phase 1 study of KTE-C19 in adult patients with r/r acute lymphoblastic leukemia. A phase 2 study is planned for later this year. CYRX noted that they are supporting all of Kite's current seven clinical trials including for their T cell receptor candidate being developed for the treatment of solid tumors. While the initial market for KTE-C19 (in DLBCL) is expected to be similar to that for CTL019's similar (i.e. second) indication (~7k U.S. and ~7k in EU), given the potential for relatively rapid expansion of the label of KTE-C19 in NHL, we think Kite could offer near-term growth opportunity.

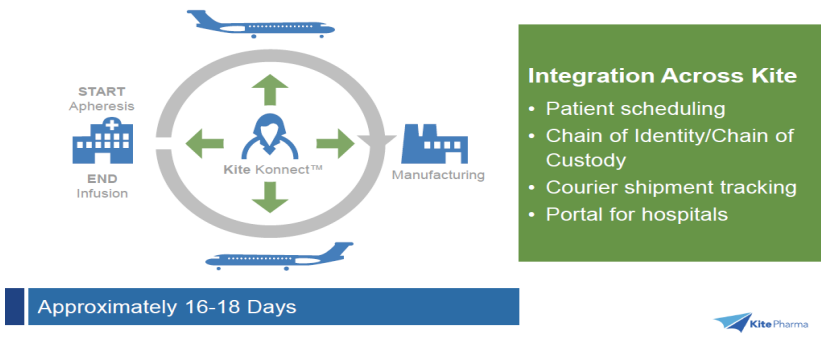
***Transport/Chain-of-Custody Is A "Complicated Process" Requiring "Special Solutions"…***

We reiterate the critical nature that transport and chain of custody plays in cell-based therapies and there is significant complexity in many of these functions. At a recent investor presentation Kite's management touched on the complexity involved in transportation, noting that (slide below from presentation), "the manufacturing is just one piece of the puzzle - it starts at the hospital with the leukapharesis, it has to go to the manufacturing and back. This is a complicated process that we had to come up with some special solutions. It needs to integrate the patient scheduling, the chain of identity, chain of custody, it has to bring into consideration the shipment in and out and the portals of the hospitals so the patient can receive it on time."

We think this, again, speaks to validation and trustworthiness of CRYX's expertise and abilities. But it also speaks to why we believe there is a significantly high barrier to entry and provides CYRX with a substantial competitive advantage.

**Transportation a "Complicated Process"**

Market Setting Integrated Delivery Solution for ***axi-cel***




SOURCE: Kite Pharma, Jefferies Global HC Conf June 2017

**Valuation: $8/share**

A large study assessing clinical development success rates found that approximately 50% of phase III candidates and 85% BLA/NDA submissions are ultimately approved for sale in the U.S. by FDA. Assuming these ratios prove to be consistent with the outcomes of CYRX's current clinical trial customer's development experiences and given our supposition that regulatory burdens and CYRX expertise provide barriers to switching to another shipping/logistics/storage provider upon commercialization, we might expect that CYRX could be supporting as many as eight commercialized products from their current phase III customers and one or both BLA candidates within the next 12 – 36 months. As noted, the first of these (Kite's KTE-C19 and Novartis' CTL019) could potentially launch later this year. Given the recent positive FDA advisory panel comments and unanimous vote to approve CTL019, we have updated our model with the assumption of a 100% chance of U.S. regulatory approval.

As CYRX's clinical customer pipeline grows, including into later stages, so does their shots on goal and opportunities for additional revenue growth. And, as we have illustrated in recent reports, CYRX's revenue growth has closely track growth in their clinical trial customer base.

Cryoport estimates that there are 855 ongoing clinical trials in the regenerative medicine space – approximately 15% of which we estimate that CYRX is currently supporting. We think the ~43% growth in the number of regenerative medicine clinical trials that the company supports over just the last nine to twelve months along with the double-digit percentage of total regenerative medicine trials that they are involved in speaks to validation of the company's offerings. This is also a major component driving our modeled continued growth of the number of supported clinical trials – which in turn, drives our modeled revenue growth.

We recently updated our valuation methodology to what we believe best represents publicly traded industry comparables of companies in the delivery and logistics/transportation sectors. Our list does not include peers solely focused on cold/cryogenic shipping of biological materials or any logistics organizations primarily operating in the biotechnology/pharmaceutical space – the reason is that, other than CYRX, there are no publicly traded companies with viable operations solely focused on those areas. We do believe, however, that there is enough crossover among our list and CYRX in terms of industry fundamentals, challenges and opportunities that it is a fair representation for comparable valuation purposes.

Average comparable PE/G (excluding high and low outliers) is 1.81 which is applied to our forecasted revenue growth rate of CYRX of 51% through fiscal 2021. The result, $11.5/share, is discounted back to the present at a CAPM-calculated discount rate of 13.1% to come to present value of approximately $8/share.

The move in our per-share target price from $6 to $8 resulted from a combination of higher comp valuations as well as from an update to our model as a result of the advisory panel recommending FDA approval of CTL019.

| | P/E | | P/S | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Delivery** | 1yr trailng | 1yr frwrd | 1yr Tr | 1yr Fr | 5yr G | P/E 4yr Fr | P/S 4yr Fr | PE/G | P/B | EV/EBITDA |
| FDX | 19.04 | 13.56 | 0.93 | 0.85 | 12.1% | 10.75 | 0.53 | 1.32 | 3.55 | 11.7 |
| UPS | 28.45 | 17.22 | 1.56 | 1.43 | 8.4% | 19.02 | 1.04 | 2.27 | 181 | 14.03 |
| DPSGY | 16.13 | 14.15 | 0.68 | 0.62 | 15.5% | 7.85 | 0.33 | ~~0.51~~ | 3.5 | 9.96 |
| ABC | 17.58 | 14.26 | 0.13 | 0.12 | 8.9% | 11.48 | 0.08 | 1.78 | 7.82 | 8.95 |
| **Logist/Transp** | | | | | | | | | | |
| CHRW | 19.19 | 18.34 | 0.073 | 0.7 | 7.3% | 13.50 | 0.05 | 2.85 | 7.45 | 12.54 |
| RLGT | 80.3 | 19.63 | 0.34 | 0.32 | 24.6% | 10.15 | 0.11 | 0.80 | 2.08 | 13.03 |
| RRTS | 10.94 | 10.26 | 0.14 | 0.13 | NA | NA | NA | NA | 0.43 | 6.49 |
| JANL | 1.87 | NA | 0.07 | NA | NA | NA | NA | NA | 0.43 | 5.15 |
| EXPD | 22.55 | 20.08 | 1.54 | 1.46 | 3.6% | 18.87 | 1.29 | ~~4.12~~ | 5.19 | 11.96 |
| HUBG | 18.4 | 17.06 | 0.34 | 0.33 | 24.0% | 6.29 | 0.12 | NA | 1.97 | 8.02 |
| LSTR | 26.13 | 21.55 | 1.13 | 1 | 13.4% | 13.94 | 0.60 | 1.83 | 6.36 | 12.88 |
| **Average** | | | | | | | | **1.81** | | |

| **Inputs** | | | **CYRX** | | | | |
|---|---|---|---|---|---|---|---|
| Treasury | Disc Rate | Ind. PE/G | Beta | 5yr G | Yr5 EPS | Yr5 Value | PV |
| 2.40% | 13.1% | 1.81 | 1.41 | 51% | $0.13 | $11.5 | **$7.93** |

## FINANCIAL MODEL

**CryoPort Inc.**
Format Reflects Calendar-Year Reporting

| | 2015 A | Q1A | Q2A | Q3A | Q4A | 2016 A | Q1 A | Q2 E | Q3 E | Q4 E | 2017 E | 2018 E | 2019 E |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total Revenues | $5,525.2 | $1,555.5 | $1,917.6 | $1,976.8 | $2,228.9 | $7,678.8 | $2,712.2 | $2,877.2 | $3,186.1 | $3,590.6 | $12,366.1 | $20,478.5 | $30,097.6 |
| *YOY Growth* | *54.7%* | *29.8%* | *34.0%* | *37.6%* | *52.8%* | *39.0%* | *74.4%* | *50.0%* | *61.2%* | *61.1%* | *61.0%* | *65.6%* | *47.0%* |
| Cost of Revenues | $3,846.6 | $973.7 | $1,135.6 | $1,180.0 | $1,288.0 | $4,577.4 | $1,458.7 | $1,611.2 | $1,736.4 | $1,931.8 | $6,738.1 | $10,218.7 | $13,875.0 |
| Gross Income | $1,678.6 | $581.8 | $782.0 | $796.8 | $940.8 | $3,101.4 | $1,253.5 | $1,266.0 | $1,449.7 | $1,658.9 | $5,628.0 | $10,259.7 | $16,222.6 |
| *Gross Margin* | *30.4%* | *37.4%* | *40.8%* | *40.3%* | *42.2%* | *40.4%* | *46.2%* | *44.0%* | *45.5%* | *46.2%* | *45.5%* | *50.1%* | *53.9%* |
| SG&A | $8,997.6 | $3,061.4 | $2,625.4 | $2,743.0 | $2,839.6 | $11,269.4 | $2,773.0 | $3,049.8 | $3,326.2 | $3,569.1 | $12,718.1 | $16,505.6 | $20,406.2 |
| *% SG&A* | *162.8%* | *196.8%* | *136.9%* | *138.8%* | *154.0%* | *146.8%* | *102.2%* | *106.0%* | *104.4%* | *99.4%* | *102.8%* | *80.6%* | *67.8%* |
| R&D | $490.8 | $144.5 | $135.8 | $214.7 | $103.1 | $598.1 | $249.8 | $221.0 | $234.0 | $228.0 | $932.8 | $848.0 | $882.0 |
| *% R&D* | *8.9%* | *9.3%* | *7.1%* | *10.9%* | *4.6%* | *7.8%* | *9.2%* | *7.7%* | *7.3%* | *6.3%* | *7.5%* | *4.1%* | *2.9%* |
| Operating Income | ($7,809.8) | ($2,624.1) | ($1,979.3) | ($2,160.8) | ($2,001.9) | ($8,766.1) | ($1,769.3) | ($2,004.8) | ($2,110.6) | ($2,138.2) | ($8,023.0) | ($7,093.9) | ($5,065.6) |
| *Operating Margin* | | *-168.7%* | *-103.2%* | *-109.3%* | *-89.8%* | | *-65.2%* | *-69.7%* | *-66.2%* | *-59.5%* | *-64.9%* | *-34.6%* | *-16.8%* |
| Other income, net | ($6.5) | ($4.9) | ($1,931.7) | ($1.4) | $1.5 | ($1,936.6) | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | ($12.0) | ($15.0) |
| Interest income, net | ($1,227.4) | ($81.2) | ($21.2) | ($19.3) | ($17.7) | ($139.4) | ($15.7) | $0.0 | $0.0 | $0.0 | ($15.7) | $0.0 | $2.0 |
| Loss on asset sale | $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 |
| Change in derivative value | $0.0 | $0.0 | $0.0 | $0.0 | ($2,265.4) | ($2,265.4) | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| Pre-Tax Income | ($9,043.7) | ($2,710.2) | ($3,932.2) | ($2,181.6) | ($4,283.5) | ($13,107.5) | ($1,785.0) | ($2,004.8) | ($2,110.6) | ($2,138.2) | ($8,038.6) | ($7,105.9) | ($5,078.6) |
| Taxes | $3.6 | $0.0 | $2.5 | $2.9 | $0.0 | $5.4 | $4.2 | $0.0 | $0.0 | $0.0 | $4.2 | $0.0 | $0.0 |
| *Tax Rate* | *0.0%* | *0.0%* | *0.1%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | | | | *0.0%* | *0.0%* | *0.0%* |
| Preferred Stck Conversion Charge | ($6,376.9) | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| Net Income | ($9,845.0) | ($2,785.6) | ($3,934.7) | ($2,184.5) | ($4,283.5) | ($13,188.4) | ($1,789.2) | ($2,004.8) | ($2,110.6) | ($2,138.2) | ($8,042.9) | ($7,105.9) | ($5,078.6) |
| *YOY Growth* | | *-29.5%* | *-40.4%* | *-18.0%* | *42.8%* | | *-35.8%* | | | | *-39.0%* | *-11.6%* | *-28.5%* |
| *Net Margin* | | *-179.1%* | *-205.2%* | *-110.5%* | *-192.2%* | | *-66.0%* | | | | *-65.0%* | *-34.7%* | *-16.9%* |
| EPS | ($1.65) | ($0.26) | ($0.28) | ($0.14) | ($0.25) | ($0.93) | ($0.10) | ($0.08) | ($0.09) | ($0.08) | ($0.35) | ($0.26) | ($0.18) |
| *YOY Growth* | | *-66.6%* | *-78.8%* | *-64.7%* | *-38.8%* | | *-61.3%* | | | | *-62.3%* | *-35.8%* | *-57.8%* |
| Diluted Shares O/S | 5,951 | 10,601 | 14,200 | 15,120 | 16,847 | 14,192 | 17,604 | 24,000 | 24,600 | 25,600 | 22,951 | 27,000 | 29,000 |

*Brian Marckx, CFA*

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## HISTORICAL ZACKS RECOMMENDATIONS




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