Zacks Small-Cap Research

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Cryoport Inc (CYRX-NASDAQ)

CYRX: Record Revenue, Inching Closer To Supporting Commercialized Product

We continue to value the company based on an industry P/E multiple (currently 30x) and discount this back to the present at 15% / year. We look for EPS of $0.14 in 2020 - based our valuation methodology, this values the stock at approximately $3 / share.

Current Price (11/28/16)	$2.40
Valuation	**$3.00**

OUTLOOK

CYRX's recent announced move into new and potentially highly synergistic opportunities add a positive wrinkle as we believe these could offer additional and complementary fuel for long-term growth. We believe revenue growth should begin to steepen in the near term, catalyzed by growth of the clinical trial customer base, progression of clients' trials to later stages and commercialization of new therapies. One recent highlight was the announcement that CYRX will be supporting a $4B (revenue) product from BMY. With 16 customers in Phase III and historic Ph III-to-commercialization conversion rate of ~50%, CYRX could be supporting several commercialized products in the not-too-distant future. Q2 along with the streak of eight straight quarters of sequential revenue growth provides additional validation of the stickiness of customer wins and our theorized incremental notching up of the revenue floor. This is a key step towards initial realization of the leverage that is inherent in Cryoport's business model.

SUMMARY DATA

52-Week High	**$3.00**
52-Week Low	**$1.03**
One-Year Return (%)	**-12.73**
Beta	**0.02**
Average Daily Volume (sh)	**17,399**
Shares Outstanding (mil)	**18**
Market Capitalization ($mil)	**$42**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**1**
Insider Ownership (%)	**13**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**80.3**
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 (June)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2016	1431 A	1437 A	1459 A	1556 A	5,882 A
2017	1918 A	1977 A	2119 E	2308 E	8,321 E
2018					15,208 E
2019					30,869 E

Earnings per Share

	Q1 (June)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2016	-$1.31 A	-$0.41 A	-$0.42 A	-$0.26 A	-$2.05 A
2017	-$0.28 A	-$0.14 A	-$0.16 E	-$0.16 E	-$0.61 E
2018					-$0.44 E
2019					-$0.14 E

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

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Q2 Fiscal 2017: Inching Closer To Supporting Commercialized Product…

CYRX reported financial results for their fiscal 2017 second quarter ending September 30th and provided a business update. Revenue continues to track our estimates, remains relatively strong and set a new high. This is the also the 8th straight quarter of consecutive revenue growth. CYRX continues to grow their customer base and the number of clinical trials that they are supporting – and while revenue has ticked up at a fairly consistent rate over the last few years, CYRX has yet to book any sales related to support of a commercialized product. When that happens – which is inching closer to reality with two clients expected to file BLA's in the coming months and completion of regulatory requirements related to supporting commercialization of the multi-billion dollar product of the (previously unnamed) large pharma customer expected to be upcoming – revenue could accelerate much more significantly.

Q2 revenue, at $2.0M, is up 38% yoy and inline with our $1.9M estimate. It is also a new record and up 3% from fiscal Q1 2017. Fueled by the consistent addition of new clients, greater overall utilization, progression of customers' clinical trial programs and exponential growth of immunotherapy development, the **biopharma** segment continues to account for the vast majority of CYRX's revenue and is driving most of the top-line growth. Biopharma revenue grew almost 64% yoy and accounted for about 70% of total revenue. With another 30 customers added during Q2 and expanding the number of clinical trials that CYRX is supporting to 100+ (from 90 as of August), including 16 phase III studies (up from 14 in August), the company continues to build a high-opportunity customer base.

From a total revenue perspective, and even more from a biopharma-related revenue perspective we think 1H 2017 should provide some confidence that at least the foundation of base demand for the company's offerings, represented by net growth in the customer base, continues to incrementally solidify. As we have indicated in our ongoing coverage of CYRX, solidifying a sufficient customer base foundation is a key step towards initial realization of the leverage that is inherent in Cryoport's business model. While the potential for variability in shipping volumes and related services, particularly as it relates to clinical trials (as well as for commercialized products), presents the possibility that revenue may be somewhat irregular quarter-to-quarter, we think recent financial performance including the streak of eight straight quarters of sequential revenue growth provides additional validation of the stickiness of customer wins and our theorized incremental notching up of the revenue floor.

We also think there is growing evidence of solidifying pre-operating leverage – as represented by gross margin improvement. Gross margin averaged almost 41% in 1H 2017, the highest on record both a quarterly and six month basis. The next best was 37.4% in fiscal Q4 2016. On an annual basis, gross margin has exhibited consistent improvement over the last few years – from 16.4% in 2014, to 29.7% in 2015 and to 32.1% in 2016. While we also think there may be some short-term volatility in gross margin, the trends are highly encouraging.

The next major milestone will be to see improvement in operating leverage. Clearly investments in people, processes and technology have shown up in the revenue growth. SG&A expense was $5.4M in 1H 2017, or about 138% of revenue – which is the best in company history. We expect this will move around as well. But, coupled with expectations of consistent revenue growth and firming up in gross margins, we think there are a lot of positive signs that suggest CYRX is creeping ever closer to the inflection point where operating income begins to improve on a regular basis.

Cash

Cash used in operating activities (ex-changes in working capital) was $1.2M and $2.4M in the three and six months ending 9/30/16. Cash balance at quarter end was $2.6M. In addition, subsequent to quarter-end CYRX raised approximately $3.7M (gross) from warrant tenders and exercises.

Inching Closer to Supporting Commercialized Product…

CYRX should not only benefit from onboarding of additional clinical trial clients and progression of currently supported programs to later stages but even more significantly from supporting these candidates if and when approved and commercialized. Management noted on the Q2 call that they are in late-stage discussions with several phase III clients related to commercialization and launch requirements – two of which expect to file Biologic License Applications (BLA) "in the coming months". One of these is Kite Pharma which (per that company's Q3 earnings release on November 9th) expects to initiate a rolling BLA submission for KTE-C19, a chimeric antigen receptor, to FDA for accelerated approval for aggressive Non-Hodgkin Lymphoma next month. If all goes well Kite believes they could have FDA approval and launch next year. CYRX noted that they are supporting all of Kite's current clinical trials including for their T cell receptor candidate being developed for the treatment of solid tumors.

In addition to these expected BLA candidates, the other potential near-term commercial-product related revenues could come from CYRX's previously announced relationship with a big pharma customer – which was revealed to be Bristol-Myers (BMY). CYRX is still somewhat tight-lipped on exactly what their role will be, although management said that they will be involved in the "cryogenic component" and will generate revenue from management fees as well as on a per-shipment basis. The specific drug that the agreement relates to has also not been disclosed, although we do know it is a multi-billion dollar monoclonal antibody - which could suggest it relates to BMY's coveted oncology portfolio (either owned or licensed by BMY). Revenue related to this relationship is expected to commence following completion of quality and regulatory requirements. We think this could be a good litmus test and potentially lead to additional follow-on services either directly related to the existing agreement or with other of BMY's products.

While the delay in kicking this program off with BMY is somewhat of a disappointment, we think that the reasons behind it may actually be a benefit to CYRX in the long-run. Management provided some interesting insight on the Q3 call relative to the strict regulatory requirements and procedures that FDA mandates for shipping biological material in order to ensure reproducibility and integrity of the cargo is maintained. Even slight changes to the shipping method or container can require demonstrating in a study that these changes resulted in no adverse consequences to the cargo.

We think that while these **strict regulatory requirements, which are perhaps somewhat of an irritant in this situation with BMY, may prove to be beneficial as they may act as a barrier to competition.** CYRX's clinical trial clients have already validated the company's storage and shipping process, procedures, methods, logistics and packaging/containers. As such and given the additional regulatory hoops necessary to switch to a different shipping and related services provider, they have an additional reason to utilize CYRX upon commercialization of their products. And while this may be viewed as somewhat of a hurdle to CYRX scoring other late-stage clinical trial customers (or those with an already commercialized product) which are currently utilizing a competing shipping/logistics/storage provider, CYRX's expertise, reputation and history should work in their favor. And clearly the BMY agreement suggests that companies are willing to switch to CYRX despite the regulatory burden of doing so – which we view as additional validation of the superiority of Cryoport's offerings and abilities, particularly as it relates to product safety and integrity.

Additional Validation of CYRX's Capabilities…

CYRX has recently been much more deliberate in their efforts to exploit their technological, logistics and expertise advantages in building their customer base. Long conversion timelines related to customers kicking the tires (i.e. validation) on CYRX's services has meant that eventual adoption can be a drawn out process. But a study conducted in collaboration with KCAS Bioanalytical and Biomarker Services (KCAS) and Heat Biologics comparing different shipping systems, including dry ice and CryoPort Express, and the impact on the integrity of biological cargo could provide another compelling marketing message and help to speed customer onboarding.

The study found that more than one-third of biomarkers shipped by dry ice were negatively impacted. These temperature excursions often result in compromised integrity of biological material and in cell viability. Management noted on the Q3 call that results from this study have already helped to generate interest from additional potential pharma and biotech customers. This type of validation should facilitate greater and more widespread acceptance of Cryoport as the preeminent provider of cryogenic shipping.

CYRX also appears to be gaining more widespread attention in the industry as a whole and in October won the "2016 Cold Chain Global Forum Excellence Award" in the category for "Most Effective Risk Assessment, Evaluation and Mitigation for Transportation". Specifically the award related to CYRX's complete turnkey solution for a client's fleet of cryogenic shipping requirements for animal vaccines (while not mentioned, likely relates to Zoetis) - which resulted in the customer saving an estimated $1.6M in annual costs.

Revenue Opportunity Grows with Later Stage Trials, Commercialization

CYRX's clinical trial pipeline has rapidly grown, from supporting 52 studies as of November 2015 to 59 (including 10 in phase III) at February to 78, including 13 in phase III at June 2016 to 100+ including 16 in phase III, today. We think garnering this number of clinical trials in a relatively short period is a powerful endorsement for CYRX's capabilities. Opportunity in this segment is where we continue to see the bulk of CYRX revenue growth emanating from, particularly in the near-to-mid terms.

And while supporting clinical trials can be a meaningful revenue contributor, logistics and shipping support for a commercialized product could be much more significant. For reference management estimates that the potential

revenue range for support of a phase I program is $15k - $75k, phase II is $50k - $150k, phase III is $200k - $1M and for a commercialized product is $3M - $20M.

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 (above) that regulatory burdens 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 of the two (upcoming) BLA candidates within the next 12 – 36 months. As noted, the first of these could potentially launch next year. As CYRX's clinical customer pipeline grows, including into later stages, so does their shots on goal and opportunities for additional revenue growth.

Synergistic Opportunities…
We think the impetus for CYRX's recent move into new synergistic ventures including the partnership with Worthington Industries (Taylor-Wharton), launch of a logistics consulting division and entry into the bio-storage market via a partnership with Pacific Bio-Material Management was not just related to increasing the volume of revenue-generating opportunities but also likely to expand their capabilities to better support their existing and growing client base. The BMY relationship fits this theme and potentially allows CYRX to better support a greater portion of the cold shipping and storage value chain. It also affords CYRX opportunity to broaden their marketing and capabilities message to one where they will be involved in the entire end-to-end shipping, bio-storage and logistics process, providing the value-add of one-stop shop and customer security that responsibility for payload remains at a single point of contact.

CYRX recently expanded menu of capabilities includes…

- **Bio-Storage**: June 15th CYRX announced a partnership with Pacific Bio-Material Management Inc whereby they will now provide bio-storage. CryoPort Biostorage will provide cryogenic storage, fulfillment and transportation of biological material. We view biostorage as a particularly critical portion of the cold shipping/storage value chain as this provides not only synergistic benefits to CYRX's shipping and logistics capabilities but also means that they maintain possession of customers' cargo from collection, transport and storage - value-add that can be critical to a customer. CryoPort Biostorage launched in June

- **Laboratory Relocation Service**: concurrent with the biostorage announcement, CYRX noted that they will provide a lab relocation service whereby they will provide safe and secure transport of complete laboratories. The lab relocation service launched in June

- **Worthington Industries Partnership**: on April 13th CYRX announced a partnership with Worthington Industries (WOR), a $2B+ (market cap) metals manufacturing company which diversified into cryogenic containers for shipping and storage with the December 2015 purchase of Taylor-Wharton's CryoScience business. CryoScience's product page can be found at this link (http://worthingtonindustries.com/Products/CryoScience-Products).

  While CYRX has not provided specifics what the partnership will entail, they have noted that Worthington "will design and manufacture biostorage and logistics equipment for use in Cryoport's life sciences cryogenic logistics solutions." CYRX has further indicated that Worthington may be involved in manufacturing next-gen Cryo shippers for CYRX as well as potentially biostorage products. Biostorage would move CYRX into another and new (to them) part of the cryogenic value chain. While this is not necessarily in the company's 'wheelhouse' of expertise it is complementary to their core business and represents a potential new revenue opportunity. It also would have synergistic sales/marketing benefits such as being able to detail the offering at the same call points as their shipping and logistics services (i.e. – it's an 'add-to-the-bag' opportunity) .

- **Logistics Consulting Service Launched**: on April 11th CYRX announced formation of a Temperature Controlled Logistics Consulting Division aimed at helping cell-based life sciences companies navigate the intricacies of global cold chain shipping and storage. Tamie Joeckel, who joined CYRX earlier this year and who has significant expertise in pharmaceutical shipping and logistics is heading the newly formed division. We have yet to model any potential contribution from this new logistics consulting business and expect to hear more details about it from the company in the near future. CYRX noted on the Q1 call that the logistics consulting service is now operational

Among the highlighted announcements related to new accounts are;

- **Feb 16**: will manage shipping of solid tumor samples and Perseus PCI's immunotherapy cancer vaccine for their melanoma and ovarian cancer clinical trials from the company's lab in South Carolina to various U.S.-based clinical sites.
  Per clinicaltrials.gov (https://clinicaltrials.gov/ct2/show/NCT02301611), a phase IIb melanoma clinical trial is underway and expected to enroll a total of 120 stage III and IV melanoma patients. Clinicaltrials.gov lists 14 clinical sites that are currently recruiting for this melanoma study. We were unable to find publicly available information (Perseus is privately held) on the ovarian cancer program.

- **March 3**: will support cryogenic logistics of ImmunoCellular Therapeutics' (IMUC) randomized phase III glioblastoma clinical trial of its cancer immunotherapy candidate, ICT-107. The trial will be conducted at 120 clinical sites in North America and Europe. Per clinicaltrials.gov (https://clinicaltrials.gov/ct2/show/NCT02546102?term=ICT-107&rank=2) estimated enrollment is 414 patients. Per CYRX, this is one of the largest clinical trials that the company has supported. Given the relatively large patient size and clinical site diversity, we view this study in particular as another meaningful vote of confidence in CYRX's shipping and logistics capabilities and reliability in maintaining the integrity of clinical trial samples and, importantly, being able to validate this. Assuming CYRX's success in meeting IMUC's requirements, the scope of this type of contract is one which affords 'feather-in-cap' status in our opinion and one which can be influential for marketing the company's capabilities.

- **April 4:**: ProteoGenex will use CYRX's solutions for shipment of their biological specimens. ProteoGenex is a Culver City, CA-based biorepository ("over 200k individual biomaterials") which provides specimens of human tissue and blood and other fluids for clinical trials and other research purposes. ProteoGenex's website touts their quality control program, speed and reliability, size and quality of its biorepository and the fact that its specimens have been used in hundreds of peer-reviewed research publications as reasons why customers should use its products. CYRX's press release announcing the new account states that ProteoGenex will abandon their legacy dry-ice shipping method in favor of CryoPort's and that the two companies are in process of making that transition.

- **May 6**: Cryo Store B.V., a Dutch provider of biostorage, packaging and logistics has agreed to use CYRX for end-to-end cryogenic shipping and logistics for biomaterial shipping to and from its pharmaceutical customers.

- **May 23**: CYRX, utilizing their S. California and Singapore depots, will provide logistics support for International Stem Cell Corp's phase I clinical trial in Australia for their Parkinson's disease candidate.

- **June 8**: Tissue Solutions, a tissue biobank with a global customer base, will use CYRX's logistics, dewars and Smart Pak II monitoring system to ship tissue from collection sites to clients based all across the world.

- **August 2**: "One of the world's foremost (unnamed) contract manufacturers to the biopharma industry ("the Client") will convert its fleet of liquid nitrogen dewars supporting shipping of its contract manufacturing biologics and cell therapy businesses to Cryoport's industry-leading and comprehensive logistics solutions." CYRX has not disclosed specifics in terms of the scope or expected volume of services related to this relationship although we hope to hear more in the future

- **August 11**: Stemedica Cell Technologies, which has used CYRX services since last year, recently entered an agreement for CYRX to support that company's phase II clinical trial (n=40) for their allogenic stem cell candidate for the treatment of Alzheimer's

- **September 22**: Integrated Solution with Database Integrations: CryoPortal integrated into Database Integration's Integrated Cell Therapy Automated Network (iCAN) scheduling platform. Integration allows for seamless scheduling, manufacturing and transport of cell-based therapies.

- **November 3**: CYRX will provide logistics services to Lattice Biologics and their AmnioVisc joint-relief product which is derived from amniotic fluid)

Valuation

We continue to value the company based on an industry P/E multiple (currently 30x) and discount this back to the present at 15% / year. We look for EPS of $0.14 in 2020 - based our valuation methodology, this values the stock at approximately $3 / share. We note that we have only incorporated incremental contribution from support related to the BMY relationship and other potential commercialization-support opportunities that may arise over the next 12

- 18 months. We have also yet to model the expanded service offerings including biostorage, lab relocation and logistics consulting. Depending on actual contribution, our revenue and earnings estimates - and therefore our price target, could prove conservative. Our model and price target are therefore highly subject to change.

FINANCIAL MODEL

CryoPort Inc.

	2016 A	Q1 A	Q2 A	Q3 E	Q4 E	2017 E	2018 E	2019 E	2020 E
Total Revenues	$5,882.2	$1,917.6	$1,976.8	$2,118.8	$2,307.8	$8,320.9	$15,207.8	$30,868.5	$45,285.4
YOY Growth	*49.5%*	*34.0%*	*37.6%*	*45.3%*	*48.4%*	*41.5%*	*82.8%*	*103.0%*	*46.7%*
Cost of Revenues	$3,991.9	$1,135.6	$1,180.0	$1,313.6	$1,419.3	$5,048.5	$8,100.3	$14,606.0	$19,864.0
Gross Income	$1,890.3	$782.0	$796.8	$805.1	$888.5	$3,272.4	$7,107.5	$16,262.5	$25,421.4
Gross Margin	*32.1%*	*40.8%*	*40.3%*	*38.0%*	*38.5%*	*39.3%*	*46.7%*	*52.7%*	*56.1%*
SG&A	$10,080.9	$2,625.4	$2,743.0	$3,262.9	$3,600.1	$12,231.4	$15,511.9	$18,644.6	$21,284.1
% SG&A	*171.4%*	*136.9%*	*138.8%*	*154.0%*	*156.0%*	*128.0%*	*102.0%*	*60.4%*	*47.0%*
R&D	$550.3	$135.8	$214.7	$212.0	$218.0	$780.5	$740.0	$785.0	$825.0
% R&D	*9.4%*	*7.1%*	*10.9%*	*10.0%*	*9.4%*	*9.4%*	*4.9%*	*2.5%*	*1.8%*
Operating Income	($8,740.9)	($1,979.3)	($2,160.8)	($2,669.8)	($2,929.6)	($9,739.4)	($9,144.4)	($3,167.0)	$3,312.3
Operating Margin	*-148.6%*	*-103.2%*	*-109.3%*	*-126.0%*	*-126.9%*	*-117.0%*	*-60.1%*	*-10.3%*	*7.3%*
Other income, net	($9.9)	($1,931.7)	($1.4)	($4.0)	($1.5)	($1,938.7)	($12.0)	($15.0)	$6.0
Interest income, net	($1,065.9)	($21.2)	($19.3)	($18.3)	($16.8)	($75.6)	$0.0	$2.0	$16.0
Loss on asset sale	$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	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($9,816.7)	($3,932.2)	($2,181.6)	($2,692.0)	($2,947.9)	($9,815.0)	($9,156.4)	($3,180.0)	$3,334.3
Taxes	$3.6	$2.5	$2.9	$0.0	$0.0	$5.4	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.1%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Preferred Stck Conversion Charge	($4,474.3)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	($15,057.4)	($3,934.7)	($2,184.5)	($2,692.0)	($2,947.9)	($9,820.4)	($9,156.4)	($3,180.0)	$3,334.3
YOY Growth	*23.5%*	*-40.4%*	*-18.0%*	*-10.3%*	*5.8%*	*-34.8%*	*-6.8%*	*-65.3%*	*-204.9%*
Net Margin	*-256.0%*	*-205.2%*	*-110.5%*	*-127.1%*	*-127.7%*	*-118.0%*	*-60.2%*	*-10.3%*	*7.4%*
EPS	($2.05)	($0.28)	($0.14)	($0.16)	($0.16)	($0.61)	($0.44)	($0.14)	$0.14
YOY Growth	*-15.7%*	*-78.8%*	*-64.7%*	*-62.3%*	*-38.5%*	*-70.4%*	*7.7%*	*-65.2%*	*-155.2%*
Diluted Shares O/S	7,347	14,200	15,120	17,200	18,250	16,193	20,750	22,000	23,000

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