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Zacks Small-Cap Research

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Brian Marckx, CFA
bmarckx@zacks.com
Ph (312) 265-9474

scr.zacks.com

10 S. Riverside Plaza, Chicago, IL 60606

Cryoport Inc (CYRX-NASDAQ)

CYRX: Close Of Record-Setting Year, Commercial Pipeline Represents Next Revenue Inflection

We us an average comparable PE/G ratio of 1.9 which is applied to our forecasted revenue growth rate of CYRX of 51% through fiscal 2022 and discounted it back to the present at a CAPM-calculated discount rate of 14.7% to come to present value of approximately $11/share.

Current Price (03/09/18)	$9.98
Valuation	**$11.00**

OUTLOOK

CYRX is in a potentially enviable position given their relative dominance in high-value cryogenic logistics, shipping and support, recent rapid growth of the regenerative medicine market and changes at FDA designed to streamline approval processes.

The number of regenerative medicine clinical trials has grown at a CAGR of more than 20% over the last few years and, catalyzed by a near doubling of investment dollars that poured into the space over the last 12 months, is expected to remain robust.

Accelerated pathways such as RMAT are an incentive for development and should further promote investment in regenerative therapies. Growth and increased investment in the regenerative medicine market appears to already be benefitting CYRX, which mentioned on the Q4 call that they recently revised the number of BLAs/EMAs that they anticipate supporting in 2018 from 2 - 4 to 5 - 7. With ~85% of these filings expected to result in approvals and CYRX having already supported their respective clinical trials, the company could more than triple the number of commercial therapies that they support (from two, currently) within the next 9 – 12 months. Moving PT to $11/share.

SUMMARY DATA

52-Week High	**$10.40**
52-Week Low	**$1.96**
One-Year Return (%)	**168.79**
Beta	**1.20**
Average Daily Volume (sh)	**106,202**
Shares Outstanding (mil)	**28**
Market Capitalization ($mil)	**$276**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**23**
Insider Ownership (%)	**9**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**62.1**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**N/A**
P/E using 2019 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Growth**
Industry	**Shipping**

ZACKS ESTIMATES

Revenue
(in '000s of $)

	Q1 (Mar)	Q2 (June)	Q3 (Sep)	Q4 (Dec)	Year (Mar)
2017	2712 A	2917 A	3003 A	3322 A	11,954 A
2018	3680 E	4252 E	4924 E	5564 E	18,420 E
2019					33,024 E
2020					42,135 E

Earnings per Share

	Q1 (June)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2017	-$0.10 A	-$0.08 A	-$0.08 A	-$0.09 A	-$0.34 A
2018	-$0.09 E	-$0.08 E	-$0.07 E	-$0.07 E	-$0.31 E
2019					-$0.13 E
2020					-$0.05 E

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

Q4 2017: Close Of Record-Setting Year, Commercial Pipeline Represents Next Revenue Inflection…

Cryoport (CYRX) reported Q4 financial results and provided a business update. Revenue came in moderately below our number – most of which we think relates to difference in mix of clinical trials that the company supports, and operating expense higher than what we modeled – which almost certainly relates to additional spend as the company beefs up capabilities in anticipation of ramping commercialization-support activities.

We have zero concerns about the difference to our estimates as CYRX remains a growth story and one that appears to be further solidifying. Management's updates on the call included an increase in the anticipated number of customers' BLA filings in 2018 from 2 – 4 to 5 – 7. With ~85% of these filings expected to result in approvals and CYRX having already supported their respective clinical trials, the company could more than triple the number of commercial therapies that they support (from two, currently) within the next 9 – 12 months.

Revenue

Q4 revenue, at $3.3M was up 49% yoy and 11% sequentially, although about 7% below our estimate. Nonetheless this was a new record high. For the full year, revenue grew 56% to $11.95M, up from $7.68M in 2016. Biopharma, which accounted 76% of total sales in both Q4 and the full year, was again the main catalyst in driving the top line growth. It was not, however, the only highlight as Animal Health revenue was up a beefy 42% qoq in Q4 and the highest on record. This segment also turned in 34% growth for the year and, per management's comments on the call, should see additional growth in 2018.

Q4 results compared to our estimates; biopharma: $2.52M A vs. $2.87 E, Δ = -12%, reproductive medicine: $454k A vs. $419k E, Δ = +8% and animal health: $352k A vs. $246k E, Δ = +43%.

Relative to biopharma, revenue increased 63% yoy and 7% sequentially in Q4. It was up 72% for the full-year 2017. CYRX added 19 new clinical trials in Q4, while we had estimated an add of 20. The miss to our Q4 revenue number relates to the clinical trial multiple declining more than we had anticipated – but with ~12% of the current clinical trial roster represented by phase III studies (versus 10% in Q2 and Q3 2017) and the total number of trials supported continuing to grow (85 net new trials were added during 2017), we think near-term sequential growth of the biopharma segment will steepen.

This segment, which now accounts for 76% of total revenue, up from 69% in 2016, continues to be the main driver of the top-line. Onboarding of new biopharma clients and clinical trials has been the major catalyst driving revenue of this segment. Growth in the clinical trial roster is also indicative of CYRX's capabilities and almost certainly helping to drive awareness of their unmatched expertise in cryogenic shipping and logistics. As we explain below, while growth in the clinical trial customer base has been the main driver of CYRX's success to-date, that could soon be eclipsed by contribution related to supporting commercialized products.

Relative to animal health, Q4 revenue was $352k – up 62% yoy and 42% sequentially. For the full year, revenue grew 34%. Some of the Q4 growth was attributed to a cell bank move for a new client, although management also indicated that most of the upside was organic and that they think this segment will continue to show robust growth through at least 2018. A variety of influences have benefitted this business including the recent addition of clinical trials, CYRX's partnership with Zoetis and growth in demand for veterinary vaccines and certain regenerative medicines. More recently, the international relocation of cell banks for a new European customer (Boehringer-Ingelheim) was cited as a significant contributor to animal health revenue. Management also noted that an increase in the number of clinical trials as well as onboarding of new vaccine trials, which are anticipated to commence in the near-term, should steepen revenue growth in 2018.

Relative to reproductive medicine, Q4 revenue was $454k – down 2% yoy and up 3% qoq. For the full year, this segment was up 11% and accounted for 14% of total revenue. The catalysts and (partially offsetting) headwinds have remained fairly constant as of late. The catalyst side includes a very frothy domestic IVF market which has been furthered stoked by Cryoport's targeted marketing campaigns. This helped push domestic revenue up by 44% in 2017.

We also like the macro fundamentals of the domestic IVF market. New technologies related to egg-freezing, more accurate and less-invasive diagnostics and the fact that IVF can be a highly profitable business (and not reliant on third-party reimbursement) have all been cited as reasons for a recent spike in private equity investments in IVF clinics. Frothiness of the IVF space has also prompted consolidation. In fact, Combimatrix, a diagnostics company focused on women's health and a client of CBMX's was recently acquired by Invitae (NVTA). Combimatrix's recently launched proprietary IVF test was already one of the company's most profitable and fastest growing products.

Meanwhile, CYRX's international reproductive medicine segment continues to struggle. Revenue was down 33% in 2017 due to recently implemented restrictions related to medical tourism by certain countries. Nonetheless, we think this business as a whole as room to grow given relative strength in the domestic market as well as CYRX's active measures to accelerate activity which included the deployment of additional shippers, targeted awareness-building campaigns and the new CryoStork Next Flight Out service (which launched in early 2017).

Gross Margin, OpEx
Q4 gross margin was 51.6% - while down from 53.5% in Q3, it's well ahead of our 49.0% estimate. We also note that Q3 margin was a very tough comp to beat given that it was an all-time high and 570 basis points wider than the previous best. So Q4's GM is second highest on record and, more importantly, we had expected some short-term variability and management continues to guide for this to eventually reach 60%.

For the full year, GM was 49.9%, compared to 40.4% in 2016. Margin improvement has been attributed to a combination of pricing increases and operational efficiencies leveraged with higher business volumes. While we continue to expect fairly regular widening of gross margin, we note that it may continue to show some q-to-q volatility. Nonetheless, we model gross margin to average 54% throughout 2018 and believe management's goal of eventually reaching 60% is realistic.

Meanwhile, operating expenses were $4.0M, meaningfully higher than our $3.5M estimate as well as compared to Q3 ($3.6M). But as noted, we have no concern about the recent higher expense levels given that these relate to investments in personnel and capacity and capabilities-related additions and improvements. As management has noted on recent conference calls, if the only goal was to be profitable, they could do that now by slashing costs – the capabilities and capacity investments that these incremental expenses relate to allow the company to meet an upcoming ramp in demand – which in-turn should result even greater operating leverage when revenue ramps.

For the full year operating expenses were $13.9M – while an increase of 17% from 2016 ($11.9M), it's worth noting that revenue grew at an even faster rate of 56%. And, coupled with the 950 basis point widening of gross margin over the same period, resulted in operating loss improving from $8.8M in 2016 to $7.9M in 2017.

Cash
Cash flow information will be available when CYRX files their 10-K - expected to be later today. They did report on EBITDA in the earnings release: EBITDA was -$1.08M and -$3.67M in the three and 12 months ending 12/31/17, compared to -$1.12M and -$5.28M in the comparable year-earlier periods. Cash balance at year-end was $15.0M and, subsequently, an additional $4.7M cash was raised via warrant exercises.

Operational Update:

Biopharma: Of the current 214 clinical trials that CYRX is currently supporting, the majority are in the regenerative medicine space – the outsized growth of that market over just the last few years has clearly created demand-pull for cryogenic shipping and related services. And clearly CYRX, with their expertise in cryogenic shipping and logistics including their real-time temperature monitoring and tracking capabilities, has been the beneficiary of the strict requirements aimed at ensuring the safety and viability of biological material during handling, transport and storage. Current estimates are that more 946 regenerative-medicine clinical trials are now ongoing.

Importantly, CYRX not only continues to grow the number of clinical trials they are supporting, but also continues to consistently grow the number of late-stage trials it supports – they now support 26 phase III and 93 phase II trials, up from 18 and 58, respectively, one-year ago. Later stage trials, which typical have significantly larger patient enrollments than earlier phases, offer similarly greater revenue potential to CYRX.

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 $75k - $125k, phase III is $200k - $1M and for a commercialized product is $2M - $20M.

Rapid Growth of Regenerative Market, Regulatory Submissions
CYRX is in a potentially enviable position given their relative dominance in high-value cryogenic logistics, shipping and support, recent rapid growth of the regenerative medicine market and changes at FDA designed to streamline approval processes.

The number of regenerative medicine clinical trials has grown at a CAGR of more than 20% over the last few years and, catalyzed by a near doubling of investment dollars that poured into the space over the last 12 months, is expected to remain robust.

FDA has helped facilitate growth of this market. Regenerative Medicine Advanced Therapy (RMAT) designation, part of the new 21st Century Cures Act, provides an accelerated approval pathway for regenerative medicine therapies that target unmet needs for serious diseases and conditions and which have shown initial efficacy. Per FDA's November 2017 Draft Guidance related to expedited approval pathways, RMAT was established because "CBER recognizes the importance of regenerative medicine therapies and is committed to helping ensure they are licensed and available to patients with serious conditions as soon as it can be determined that they are safe and effective."

Accelerated pathways such as RMAT are an incentive for development and should further promote investment in regenerative therapies. As of February 2018 14 RMAT designations had been granted. The most recent available data also shows that there were 550 IND's active as of September 2017 related to regenerative therapies, 76 of which were for CAR-T therapies.

Growth and increased investment in the regenerative medicine market appears to already be benefitting CYRX, which mentioned on the Q4 call that they recently revised the number of BLAs/EMAs that they anticipate supporting in 2018 from 2 - 4 to 5 - 7. With ~85% of these filings expected to result in approvals and CYRX having already supported their respective clinical trials, the company could more than triple the number of commercial therapies that they support (from two, currently) within the next 9 – 12 months.

Growing Commercial Pipeline Indicates The Next Revenue Inflection Is On The Horizon…
With each commercial contract expected to generate in the range of $2M - $20M per year, CYRX could very likely be heading into 2019 with a commercial-support portfolio worth at least $18M in just the first year. And $18M could prove highly conservative, depending on the ramp of their two current commercial contracts, Yescarta and Kymriah, as well as the respective value of the commercial markets of the outstanding BLAs.

With indications that commercial activities of both of their currently-supported CAR-T products are accelerating and CYRX beefing up infrastructure (including opening two new logistics centers and upgrading software and tracking) and support functionality (including adding headcount) to meet the anticipated new demand, all indications are that commercial-support related revenue should soon begin to make a meaningful contribution.

And for a variety of reasons, indications also suggest that CYRX's commercialization-support revenue could steepen in fairly short order. Gilead/Kite (Yescarta) and Novartis (Kymriah) are aggressively pursuing additional indications for their recently approved respective CAR-T therapies, success of which will automatically bolt on additional revenue opportunity for CYRX. And, in addition to their current roster of filed BLA's, CYRX has a potential pipeline of 214 more – which represents the current number of clinical trials that they support.

And while most early-stage candidates will fail to reach the market, those odds are greatly improved with progression to later stages. Of the 93 phase II and 26 phase III trials that CYRX currently supports, it's reasonable that 15 to 20 will result in approved indications over the next two to five years' time – which would represent incremental annual revenue to CYRX of anywhere between $30M and $400M.

Valuation: $11/share

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 946 ongoing clinical trials in the regenerative medicine space – over 20% of which CYRX is supporting. CYRX's clinical trial base increased from 129 one year ago to 214 today. The continued rapid growth in the number of trials has been the main catalyst to the company's total revenue growth but also speaks to validation of the company's offerings and unmatched expertise in cryogenic shipping, logistics and support. But while growth in the clinical trial customer base has been the main driver of CYRX's success to-date, that could soon be eclipsed by contribution related to supporting commercialized therapies.

CYRX expects their two new logistics centers (one in the U.S. and one in the Netherlands) to be operational around mid-year, which coincides with expected acceleration in roll out of NVS's and Gilead's CAR-T therapies. Gilead recently noted that they expect to have enough patient care centers certified to treat 5k patients by mid-2018.

We model only incremental contribution from Yescarta and Kymriah in 1H 2018 but growing a more substantial impact in the second half. Revenue potential to CYRX for just the initial indications are estimated to be $8M - $10M per year for each therapy within the first three years. With additional indications already having been filed for approval and additional approvals likely in Europe, just these two therapies could represent several 10s of millions of dollars in annual revenue to CYRX over time.

We us an average comparable PE/G ratio of 1.9 which is applied to our forecasted revenue growth rate of CYRX of 51% through fiscal 2022 and discounted it back to the present at a CAPM-calculated discount rate of 14.7% to come to present value of approximately $11/share.

Inputs			CYRX				
Treasury	Disc Rate	Ind. PE/G	Beta	5yr G	Yr5 EPS	Yr5 Value	PV
2.97%	11.6%	1.90	1.23	47%	$0.17	$15.2	**$10.92**

FINANCIAL MODEL

CryoPort Inc.

	2016 A	Q1 A	Q2 A	Q3 E	Q4 A	2017 A	Q1 E	Q2 E	Q3 E	Q4 E	2018 E	2019 E	2020 E
Total Revenues	$7,678.8	$2,712.2	$2,917.4	$3,002.7	$3,322.0	$11,954.3	$3,680.0	$4,252.4	$4,924.4	$5,563.5	$18,420.3	$33,024.0	$42,135.1
YOY Growth	39.0%	74.4%	52.1%	51.9%	49.0%	55.7%	35.7%	45.8%	64.0%	67.5%	54.1%	79.3%	27.6%
Cost of Revenues	$4,577.4	$1,458.7	$1,524.2	$1,396.2	$1,608.8	$5,987.8	$1,876.8	$2,134.7	$2,344.0	$2,559.2	$8,914.7	$14,266.4	$17,064.7
Gross Income	$3,101.4	$1,253.5	$1,393.2	$1,606.5	$1,713.3	$5,966.4	$1,803.2	$2,117.7	$2,580.4	$3,004.3	$9,505.6	$18,757.6	$25,070.4
Gross Margin	40.4%	46.2%	47.8%	53.5%	51.6%	49.9%	49.0%	49.8%	52.4%	54.0%	54.0%	56.8%	59.5%
SG&A	$11,269.4	$2,773.0	$3,026.3	$3,249.8	$3,604.1	$12,653.2	$3,771.9	$4,103.6	$4,264.5	$4,517.6	$16,657.7	$21,135.4	$24,859.7
%SG&A	146.8%	102.2%	103.7%	108.2%	108.5%	105.8%	102.5%	96.5%	86.6%	81.2%	78.5%	64.0%	59.0%
R&D	$598.1	$249.8	$230.7	$344.8	$380.3	$1,205.7	$355.0	$365.0	$377.0	$375.0	$1,472.0	$2,074.0	$2,285.0
%R&D	7.8%	9.2%	7.9%	11.5%	11.4%	10.1%	9.6%	8.6%	7.7%	6.7%	8.0%	6.3%	5.4%
Operating Income	($8,766.1)	($1,769.3)	($1,863.9)	($1,988.1)	($2,271.2)	($7,892.5)	($2,323.8)	($2,350.9)	($2,061.1)	($1,888.3)	($8,624.1)	($4,451.7)	($2,074.3)
Operating Margin	-89.8%	-65.2%	-63.9%	-66.2%	-68.4%	-66.0%	-63.1%	-55.3%	-41.9%	-33.9%	-46.8%	-13.5%	-4.9%
Other income, net	($1,936.6)	$0.0	$3.5	$8.5	$2.4	$14.3	$3.2	$2.1	$1.5	$1.0	$7.8	($15.0)	$6.0
Interest income, net	($139.4)	($15.7)	($0.0)	$0.0	$0.0	($15.7)	$0.0	$0.0	$0.0	$0.0	$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	$0.0	$0.0	$0.0	$0.0
Change in derivative value	($2,265.4)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($13,107.5)	($1,785.0)	($1,860.5)	($1,979.7)	($2,268.8)	($7,893.9)	($2,320.6)	($2,348.8)	($2,059.6)	($1,887.3)	($8,616.3)	($4,464.7)	($2,052.3)
Taxes	$5.4	$4.2	$0.0	$0.0	$0.9	$5.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	0.0%	-0.2%	0.0%	0.0%	0.0%	-0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Charge	$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
Net Income	($13,188.4)	($1,789.2)	($1,860.5)	($1,979.7)	($2,269.7)	($7,899.0)	($2,320.6)	($2,348.8)	($2,059.6)	($1,887.3)	($8,616.3)	($4,464.7)	($2,052.3)
YOY Growth	34.0%	-35.8%	-52.7%	-9.4%	-47.0%	-40.1%					9.1%	-48.2%	-54.0%
Net Margin	-171.7%	-66.0%	-63.8%	-65.9%	-68.3%	-66.1%					-46.8%	-13.5%	-4.9%
EPS	($0.93)	($0.10)	($0.08)	($0.08)	($0.09)	($0.34)	($0.09)	($0.08)	($0.07)	($0.07)	($0.31)	($0.13)	($0.05)
YOY Growth	-43.8%	-61.3%	-72.0%	-44.4%	-65.1%	-62.9%					-24.9%	-68.4%	-79.4%
Diluted Shares O/S	14,192	17,604	23,966	24,632	25,546	22,937	26,746	27,850	28,400	29,000	27,999	34,000	38,000

Brian Marckx, CFA

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