

Cytori Therapeutics (CYTX - \$0.32)

Healthcare/Biotechnology

An ATI-0918 Success Could Be a New Value Driver, Additional Opportunities Exist for Habeo Cell Therapy

Ticker: **CYTX**
Rating: **Buy**
Price Target: **\$1.65**

We are resuming the coverage of Cytori Therapeutics (CYTX) with a Buy rating and a 12-month price target of \$1.65. The major investment thesis is that despite the recent setback in their Phase III scleroderma study, Habeo cell therapy could still have many additional opportunities to be successful. More importantly, the potential success of little known ATI-0918 as a possible first generic liposomal doxorubicin in Europe could be a major value driver with a lower risk value proposition.

- **Habeo cell therapy development remains promising despite setback of the STAR clinical trial.** Although the STAR pivotal study that evaluated Habeo cell therapy in scleroderma did not meet its primary endpoint, outcomes of the diffuse disease subset are encouraging. Although additional Phase III studies might be needed, we believe there are several opportunities for other indications.
- **ATI-0918 could be first generic liposomal doxorubicin in Europe.** ATI-0918 is a Caelyx-bioequivalent generic pegylated liposomal doxorubicin. A stability test is scheduled to start in 1Q18 with potential EMA submission between 4Q18 and 2Q19, and potential approval in 2020. CYTX will seek a commercializing partner for ATI-0918 in EU. We view ATI-0918 a near-term major value driver for CYTX shares as we are bullish on its commercial outlook of becoming a potential first generic liposomal doxorubicin launched in Europe. We believe 1) given that U.S. branded and generic liposomal doxorubicin prices both were sustained after generic entry, such a scenario could also happen in the EU; and 2) no competitors are in sight in the near future.
- **Habeo cell therapy operation in Japan could be a meaningful revenue source in years to come.** With a footprint already established in Japan for selling Habeo cell therapy, and currently at cash-breakeven status, we anticipate CYTX could make greater sales with more investment going forward.
- **BARDA contract for thermal burn and radiation could have upside.** With a BARDA contract in place potentially reaching up to \$106MM, we believe that successful execution of the RELIEF clinical study could add value to CYTX shares.
- **Material upside remains at the current valuation.** With a near-term revenue prospect from ATI-0918 and potential upsides from development of Habeo cell therapy, we believe CYTX shares remain undervalued at current levels. Our 12-month \$1.65 price target is based on probability adjusted sum-of-the-parts analysis.

Trading Data:

Last Price (2/20/2018)	\$0.32
52-Week High (4/10/2017)	\$2.08
52-Week Low (12/15/2017)	\$0.22
Market Cap. (MM)	\$12
Shares Out. (MM)	17,291

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-0.33A	-0.19A	-0.14A	-0.14	-0.76	NM
FY-16A	-0.41	-0.43	-0.26	-0.25	-1.28	NM
FY-15A	-0.21	-0.06	-0.05	-0.06	-0.14	NM
FY-14A	-0.14	-0.15	-0.12	-0.08	-0.48	NM

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Source: Company data & Laidlaw & Company estimates

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Investment Thesis

- **We are resuming the coverage of Cytori Therapeutics, Inc. (CYTX) with a Buy rating and a 12-month price target of \$1.65.** Cytori Therapeutics is an emerging biotech company seeking to leverage 1) proprietary adipose-derived stem and regenerative cells- (ADRCs) based Habeo cell therapy as a potential treatment in various disorders; and 2) generic liposomal doxorubicin that potentially could be launched in Europe.
- **A more near-term value driver could be that ATI-0918 potentially becomes the first generic liposomal doxorubicin launched in Europe.** ATI-0918 is a generic pegylated liposomal doxorubicin, and it is bioequivalent to Johnson and Johnson's Caelyx (The U. S. brand name: Doxil). Patents of Caelyx have already expired in Europe. CYTX acquired ATI-0918 from privately-owned Azaya Therapeutics and the company has already completed bioequivalence study. CYTX is scheduled to conduct a stability test in 1Q18 and possibly submit to EMA for approval between 4Q18 and 2Q19 with potential approval in 2020. CYTX is also seeking a commercial partner for ATI-0918 in Europe. We are encouraged by the commercial outlook of ATI-0918 as a potential first generic liposomal doxorubicin launched in Europe because 1) the scenario in the U.S. that the prices of both branded and generic liposomal doxorubicin were overall sustained despite the generic entry could also happen in Europe; and 2) no other generic Caelyx is known to likely enter the European market in the near future.
- **Habeo cell therapy development remains promising despite the setback of the STAR clinical trial.** CYTX recently reported the failure of the STAR Phase III clinical trial that evaluated Habeo cell therapy in scleroderma. However, the treatment has shown a positive trend and statistically significant improvements in a subset of patients with diffuse disease scleroderma. CYTX is scheduled to discuss with the FDA, possibly in 1H18 for the Habeo cell therapy future regulatory path in scleroderma. The probability exists that the FDA will allow for a PMA filing, which we view as a significant upside. However, it is more likely, in our opinion, that the agency might ask for additional clinical studies, possibly in the diffuse disease subset, before they are willing to review the data. In addition to in the U.S., Habeo cell therapy in scleroderma could also have opportunities in Europe and Japan. It is noted that an investigator initiated, placebo controlled 40-patient SCLERADEC-II trial that evaluates Habeo cell therapy in scleroderma is underway. The primary endpoint is the Cochin Hand Function Score at three months following treatment. The EMA suggests that a 40-patient 6-month outcome, if positive, could be eligible for approval. In addition, an Habeo cell therapy in stress urinary incontinence 45-patient clinical trial (ADRESU) in Japan is also ongoing. Improvement in urinary leakage volume with >50% reduction from baseline as measured by 24-hour urinary pad weight as primary endpoint. Patient recruitment could complete in early 2018 with possible approval in late 2019, if the outcome is positive.

A more near-term value driver for CYTX shares could be that ATI-0918 potentially becomes the first generic liposomal doxorubicin launched in Europe

Habeo cell therapy development remains promising despite the potential setback of the STAR clinical trial. SCLERADEC-II trial that evaluates Habeo cell therapy in scleroderma in Europe and ADRESU trial that evaluates Habeo cell therapy in stress urinary incontinence in Japan are examples

CYTX could expand their marketing effort to further increase their revenue from Japan if they could put in more financial resources

Our \$1.65 price target is supported by a peer comparison valuation methodology and risk-adjusted cash flow sum-of-the-part analysis.

- **Japan operation and BARDA contract could have additional upsides.** CYTX has established a Japanese infrastructure that carries out commercial and clinical development of Habeo cell therapy. Following Japan's November 2015 implementation of the Regenerative Medicine Law, their market is more accessible for cell therapy. As such, the procedures and rules for clinical development and potential approval of regenerative medicine and cell therapies have been accelerated. We believe CYTX's operation in Japan is currently cash breakeven. Management indicated that if the company had greater financial resources, CYTX could expand their marketing effort and potentially could further increase their revenue. CYTX is developing the DCCT-10 therapeutic (a cell therapy) for thermal burns under a contract with BARDA (Biomedical Advanced Research Development Authority), a division of the Department of Health and Human Services. The total value of the BARDA contract could reach up to \$106MM with \$35MM allocated through 1H17 and \$13.4MM awarded to fund RELIEF study. For the RELIEF study, the efficacy objective is to determine the potential of improving generalized healing: grafted site, partial thickness burns, and skin graft donor site.
- **Substantial upside remains at the current valuation, in our view.** With ATI-0918 as potential lead near-term value driver and potentially followed by the advancement of Habeo cell therapy in different indications, we believe CYTK is undervalued despite the recent upset of the STAR Phase III study outcome. Accordingly, our \$1.65 price target is supported by a peer comparison valuation methodology and risk-adjusted cash flow sum-of-the-part analysis. We are recommending CYTX shares to long-term oriented investors with high risk tolerance

Proprietary Habeo Cell Therapy is a Leading Adipose-Derived Stem and Regenerative Cells (ADRCs) Treatment with Multiple Opportunities Going Forward

What is Habeo Cell Therapy

Habeo cell therapy utilizes the Celution System as a proprietary device for the collection and enrichment of ADRCs as a source for the treatment of various diseases.

The company has conducted multiple clinical studies to evaluate the potential of Habeo cell therapy in different diseases.

Phase III (STAR) study did not achieve statistical significance in primary or secondary efficacy endpoints

A pre-specified subgroup analysis of more severe diffuse cutaneous scleroderma patients has shown a positive trend and statistical difference in the Cochin Hand Function Score improvements and the change of HAQ-DI.

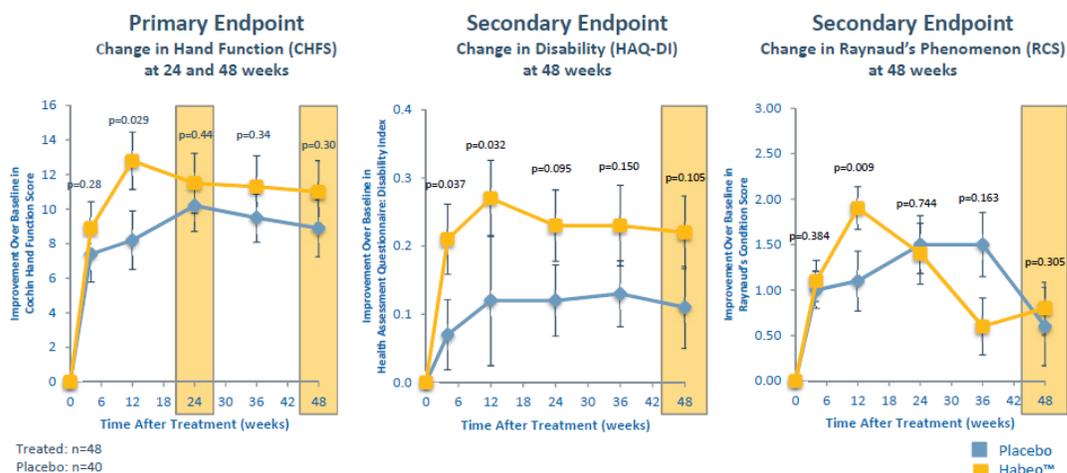
Habeo cell therapy is a proprietary cell therapy based on adipose-derived stem and regenerative cells (ADRCs) developed by Cytori. Habeo cell therapy utilizes the Celution System as a proprietary device for the collection and enrichment of ADRCs as a source for the treatment of various diseases. The process is relatively simple with three major steps: 1) a minor liposuction procedure by removing small amount of adipose tissue; 2) separate and process harvested tissues via the Celution system for the collection ADRCs; and 3) deliver ADRCs to the same individual as a treatment of various diseases. The Celution system can be placed on the bed side as a point-of-care treatment. The overall procedure is relatively short as it could take approximately one and half hours to complete ADRCs harvest and prepare them for the subsequent medical procedures.

The company has conducted multiple clinical studies to evaluate the potential of Habeo cell therapy in different diseases. A more recent example is in scleroderma. CYTX conducted a pivotal Phase III (STAR) study to evaluate single administration of Habeo cell therapy (subcutaneous) vs. placebo for the safety and efficacy in patients with hand dysfunction due to scleroderma. The primary endpoint was the improvement based on the Cochin Hand Function Score assessed at 24 and 48 weeks. Secondary endpoints include the Health Assessment Questionnaire-Disability Index (HAQ-DI) and the Raynaud's Phenomenon Condition Score. It is a randomized, double-blind, 88-patient study with 51 with diffuse cutaneous and 37 with limited cutaneous scleroderma.

CYTX reported the topline results in early 3Q17 and showed that study did not achieve statistical significance in primary or secondary efficacy endpoints (Figure 1). Specifically, for the primary endpoint in mean improvement in the Cochin Hand Function Score, Habeo cell therapy did not show statistical difference over placebo at 24 weeks and 48 weeks as determined by both analysis of covariance and mixed model repeated measure analysis.

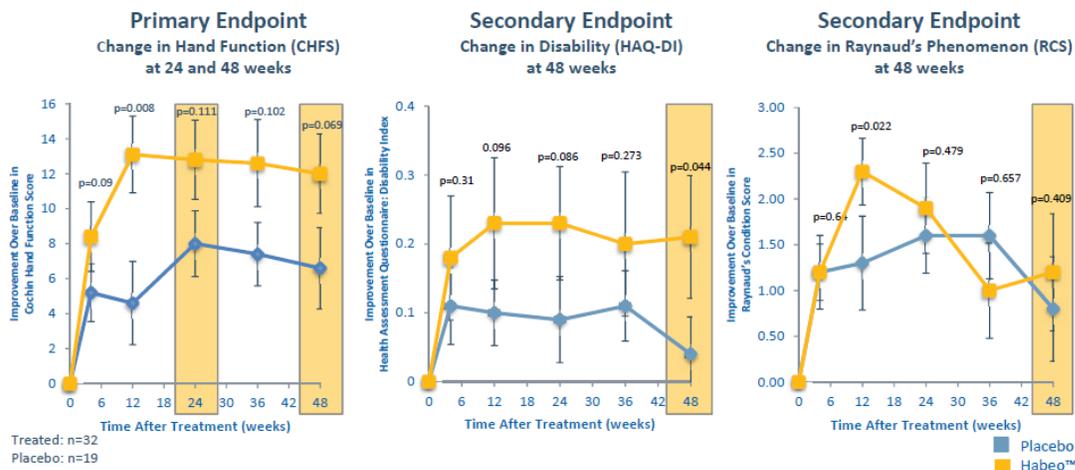
However, a pre-specified subgroup analysis of more severe diffuse cutaneous scleroderma patients has shown a positive trend and statistical difference in the Cochin Hand Function Score improvements and the change of HAQ-DI. In addition, clinically meaningful efficacy trends noted early and sustained for the two clinical endpoints (Figure 2). The Habeo cell therapy did not show any significant safety related issues.

Figure 1: Key clinical endpoints of all subjects of the STAR Phase III trial



Source: Company presentation

Figure 2: Key clinical endpoints of subjects with diffuse disease of the STAR Phase III trial



Source: Company presentation

Should the FDA request the company to conduct additional Phase III studies, possibly in the diffuse cutaneous scleroderma, CYTX might have to contemplate the availability of resources before making the decision.

The next step. CYTX plans to conduct a meeting with the FDA to determine the potential path for advancing Habeo cell therapy in scleroderma forward. Should the FDA allow Habeo cell therapy to be approved via a devices route, the company could potential submit an PMA in 2018 for possible approval. Should the FDA request the company to conduct additional Phase III studies, possibly in the diffuse cutaneous scleroderma, CYTX might have to contemplate the availability of resources before making the decision. Overall, in our opinion, we believe the probability of the latter possibility would be higher.

Scleroderma is a rare autoimmune rheumatic disorder that causes chronic connective tissue problem with hardening of the skin as a most visible manifestation. The prevalence of scleroderma in the U.S. is ~300,000 with about one-third of systemic sclerosis (SSc) or systemic form of the disease. SSc could be further classified into diffuse cutaneous (between one-third and one-half) and limited cutaneous SSc. Diffuse cutaneous SSc patients have more severe disease with significant hand dysfunction and internal organ involvement. Current

treatment recommendations for scleroderma does not have sufficient options for hand impairment.

An investigator initiated, 40-patient SCLERADEC-II trial that evaluates Habeo Cell Therapy in scleroderma in Europe is underway.

Clinical studies of Habeo cell therapy in other indications. In addition to the U.S., Habeo cell therapy might also have opportunities in other regions, like Japan and Europe. In Japan, PMDA requiring small ~20 patient non-randomized study with positive outcome for potential approval. An investigator initiated, 40-patient SCLERADEC-II trial that evaluates Habeo Cell Therapy in scleroderma is underway. The primary endpoint is the Cochin Hand Function Score at three months following treatment. Selected secondary endpoints include Raynaud’s Condition Score, HAQ-DI, and the modified Rodnan Skin Score. The EMA suggests that a 40-patient 6-month outcome, if positive, could be eligible for approval.

A Habeo cell therapy in stress urinary incontinence clinical trial (ADRESU) is underway in Japan.

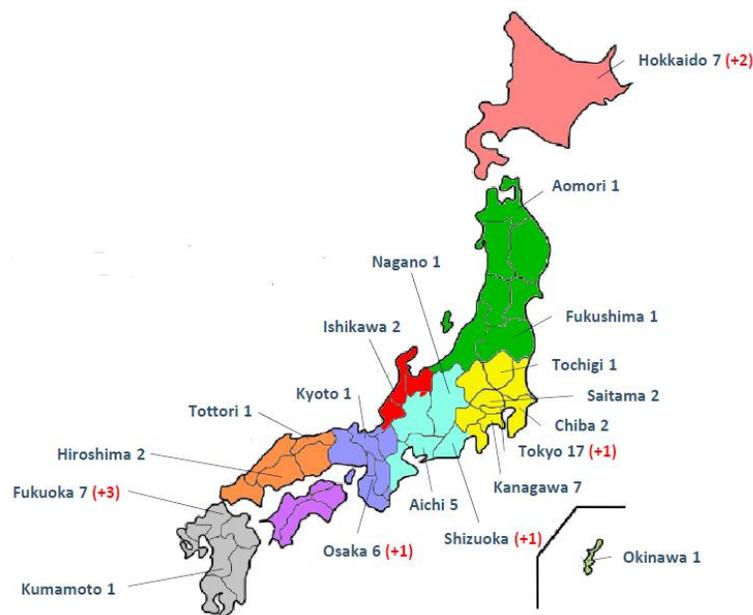
In addition, an institutional and governmental supported trial that evaluates Habeo cell therapy in stress urinary incontinence clinical trial (ADRESU) is underway in Japan. The trial is expected to enroll 45 patients with improvement in urinary leakage volume with >50% reduction from baseline as measured by 24-hour urinary pad weight as primary endpoint. Patient recruitment could complete in early 2018, with possible approval in late 2019.

Japan Commercial and Clinical Operation

CYTX has established a Japanese infrastructure that carries out commercial and clinical development.

One major differentiation of CYTX comparing to other cell therapy companies is it has established a Japanese infrastructure that carries out commercial and clinical development of Habeo cell therapy. The Celution system is currently installed in 77 sites in Japan and continues expanding (Figure 3).

Figure 3: Celution system installations in Japan



Source: Company presentation

In Japan, the use of CYTX's product were all under private pay. One of the reasons why Japan is a more accessible market for cell therapy is the government has passed the Regenerative Medicine Law in 2014 and later implemented in November 2015. As such, the procedures and rules for clinical development and potential approval of regenerative medicine and cell therapies have been accelerated. Further, CYTX could expand their clinical development with greater cost efficiency by leveraging the availability of many government- and medical institution-supported clinical studies. We believe CYTX's operation in Japan is currently cash breakeven. Management indicated that if the company has greater financial resources, CYTX could expand their marketing effort and potentially could further increase their revenue.

BARDA Contract Could Be Another Upside

CYTX is developing the DCCT-10 therapeutic (a cell therapy) for thermal burns under a contract with BARDA.

CYTX is developing the DCCT-10 therapeutic (a cell therapy) for thermal burns under a contract with BARDA (Biomedical Advanced Research Development Authority), a division of the Department of Health and Human Services. CYTX will conduct a pilot clinical trial (RELIEF) of CCT in patients with thermal burn injuries as IDE application was approved in 2Q17. The total value of the BARDA contract could reach up to \$106MM with \$35MM already allocated through 1H17 and \$13.4MM awarded via exercise of Option 2 to fund RELIEF study. CYTX has started the study for the BARDA contract since 3Q12, and based on the latest amendments, the BARDA agreement could extend to November 30, 2020.

For the RELIEF study, DCCT-10 therapeutic will be administered intravenously in up to 30 patients with large (20-50% total body surface area), 3rd-degree burns undergoing meshed skin grafting for assessing treatment's safety and feasibility. The efficacy objective of the study is to determine the potential of improving generalized healing: grafted site, partial thickness burns, and skin graft donor site.

ATI-0918 is Likely Be the First Generic Liposomal Doxorubicin in Europe With Promising Commercial Outlook

What is ATI-0918

In addition to the Habeo cell therapy, we believe CYTX's second asset, ATI-0918, could potentially be the major near-term value driver for the CYTX shares. ATI-0918 is developed by CYTX's nanomedicine operation. ATI-0918 is a generic pegylated liposomal doxorubicin, and it is bioequivalent to Johnson and Johnson's Caelyx (the U. S. brand name: Doxil). The Doxil/Caelyx is the lead product of the liposomal doxorubicin drug class globally. Patents for some branded liposomal doxorubicin already expired in the U.S. and Europe. ATI-0918 was initially developed by privately-owned Azaya Therapeutics, which CYTX acquired in 1Q17. Azaya has completed the clinical study (n=60) that demonstrated the bioequivalence of ATI-0918 to Caelyx.

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Next step. CYTX plans to submit for the EMA approval possibly either in 4Q18 or 2Q19 depending on whether the duration of the stability study would be 6 or 12 months as required by the regulatory agency. CYTX is scheduled to start the stability testing in 2Q18. In addition, CYTX will seek partner to commercialize ATI-0918 in Europe. We believe CYTX already has started active discussions with prospective partners and we estimate possible partnership could be consummated in 2018/2019. As for the potential U.S. marketing strategy, the current standard reference drug for the bioequivalence would be Lipodox (a generic of Doxil developed by Sun Pharma), which was developed and initially being imported during the 2013/2014 period due to the shortage of Doxil supply in the U.S. Given the resource constrain, CYTX will seek partner for financing before starting clinical development in the U.S. In addition, Dr. Reddy's generic liposomal doxorubicin (reference drug is Lipodox) also approved in the U.S. in 1Q17, potentially making the U.S. market even more competitive.

CYTX plans to submit for the EMA approval possibly either in 4Q18 or 2Q19 depending on whether the duration of the stability study. CYTX will seek partner to commercialize ATI-0918 in Europe.

Liposomal doxorubicin remains the cornerstone chemotherapy of multiple cancer treatments

Doxorubicin is widely used to induce regression of multiple malignancies such as many solid tumors like sarcoma, thyroid, gastric, breast, ovarian, and small cell lung cancer, and also in multiple hematological cancers, like acute lymphoblastic leukemia and acute myeloblastic leukemia. Major shortcoming of doxorubicin is its significant risk of cardiotoxicity, including congestive heart failure, when used in higher doses. As such, the objective of developing liposome encapsulated doxorubicin, like Doxil, Myocet and Lipodox, are mainly for mitigating cardiotoxicity side effects. Further, several other doxorubicin-based drug

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developments are also ongoing, such as aldoxorubicin in soft tissue sarcoma (STS) by CytRx.

It is estimated that the global doxorubicin market was approximately \$800MM in 2015. The two major markets are the U.S. (~\$400MM) and the EU (~\$280MM). Given that the regular doxorubicin is highly genericized, almost all sales are generated from different liposomal doxorubicin.

There are two liposomal doxorubicin drugs approved in the Europe: Caelyx developed by Johnson and Johnson and Myocet by Teva. Caelyx is indicated for the treatments of several types of cancer in adults, including metastatic breast cancer in patients at risk of heart problems, advanced ovarian cancer who have failed prior platinum-based anticancer, Kaposi's sarcoma in AIDS patients, and as second line therapy in combination with bortezomib in multiple myeloma.

Myocet is indicated in combination with cyclophosphamide as first-line treatment of metastatic breast cancer in adult women.

Although the active pharmaceutical ingredient of Caelyx and Myocet are identical, these two drugs are not bioequivalent. Specifically, due to different liposomal technology, the lipid composition, size and loading method for making the two drugs are different. In addition, the plasma PK and the tissue distribution pattern are also different. As such, the dosing regimen and safety profile of the two drugs are also differ.

Although liposomal doxorubicin has been approved for multiple cancer indications, it is estimated that in Europe, the majority of uses are in breast and ovarian cancers.

Promising outlook of ATI-0918. Overall, in our opinion, we believe the commercial outlook of ATI-0918 could be very promising especially if this drug potentially could be the first potential generic liposomal doxorubicin in the European market. Our bullish thesis is based on the following notions:

- **Price of liposome doxorubicin (both the branded and generic) overall has been sustained despite the entry of generic** and additional branded drugs in the U.S. For example, Doxil is charged \$1,000 per vial; while Lipodox (generic of Doxil) is approximately \$900. As such, we believe a similar scenario to what happened in the U.S. could also play out in Europe once the first Caelyx generic, like ATI-0918, enters the market. We believe the following three factors might play a critical part for the price inelasticity of the liposome doxorubicin drug class:
 - **Shortage or limitation of liposome doxorubicin supply could still be a potential issue.** One of the earlier major issues of liposome doxorubicin were the manufacturing problems in 2013, resulting in Doxil shortages across major markets globally. Although the problem was resolved later, concerns of a possible shortage caused by manufacturing issues of liposome doxorubicin in the future have not fully gone away. Case in point is that Sun Pharma recently

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encountered manufacturing issues in their Halol plant in India and is still struggling. As such, sales of Lipodox is negatively impacted. Although these are issues occurred in the U.S., it also exemplifies the potential issue of product limitation and possible, the potential shortage;

- **Manufacture of liposomal doxorubicin remains not trivial.** Although several liposomal doxorubicin, including generics, are already available in the market, the production is still difficult, evidenced by the limited number of generic and branded products available; and
- **Doxorubicin-based therapy remains an important element for multiple cancer treatments globally.** This is especially true for the liposomal doxorubicin given its more manageable toxicity profile.

No other generic Caelyx are in sight for entering the European market in the near future.

- **No other generic Caelyx are in sight for entering the European market in the near future.** One of the clinically most advanced liposomal doxorubicin development that could enter European market is TLC177 developed by Taiwan Liposome Company. The company has submitted MAA in May 2017. We have not heard any updates by the company since, and their recent public presentation did not mention anything about TLC177. As such, we speculate that TLC177 could have regulatory issues and therefore, ATI-0918 could potentially be the first generic liposomal doxorubicin entering the EU market. In addition, since Dr. Reddy's generic liposomal doxorubicin (no brand name yet) is based on Lipodox as the reference drug, which is not available in Europe, generic liposomal doxorubicin this cannot be filed or launched in Europe at the current configuration. Also, as a reminder, Myocet is a branded liposomal doxorubicin, not a generic.

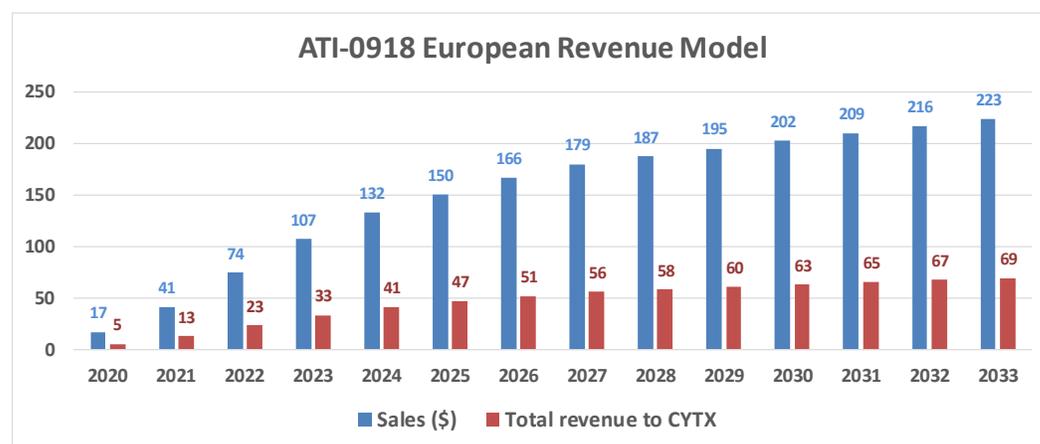
ATI-0918 in Europe revenue model. Our model (Figure 4) projects that ATI-0918 could reach the European market in 2020 assuming consummate a favorable marketing partnership. Assuming per patient annual price of \$9k (a 25% discount to that of the branded Caelyx) and potentially reach ~50+% penetration at peak of the European liposomal doxorubicin market for several cancer treatments. We also assume Cytori will manufacture ATI-0918 and receive a transfer fee for the product and also gain reasonable royalties possibly at 25%. Together, we estimate CYTX could receive annual peak sales total revenue of \$60+MM.

Figure 4a: ATI-0918 in Europe revenue model

		2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Caelyx	Cost/Rx (£)	12,017	11,416	11,587	11,761	11,937	12,116	12,298	12,483	12,670	12,860	13,053	13,248	13,447	13,649	13,854
	Cost/Rx (\$)	16,729	15,892	16,131	16,372	16,618	16,867	17,120	17,377	17,638	17,902	18,171	18,443	18,720	19,001	19,286
	Sales (\$)	243	214	195	166	143	125	117	114	114	117	121	126	130	135	139
	Sales (£)	175	154	140	120	103	90	84	82	82	84	87	91	94	97	100
Myocet	Cost/Rx (£)	12,149	12,331	12,516	12,704	12,894	13,088	13,284	13,483	13,685	13,891	14,099	14,311	14,525	14,743	14,964
	Cost/Rx (\$)	16,912	17,166	17,424	17,685	17,950	18,219	18,493	18,770	19,052	19,337	19,628	19,922	20,221	20,524	20,832
	Sales (\$)	102	108	109	109	106	105	105	104	104	107	111	115	119	123	127
	Sales (£)	73	77	78	79	76	76	75	75	75	77	80	83	86	88	91
ATI-0918	TRx	0	1,335	3,240	5,745	8,138	9,944	11,119	12,101	12,874	13,221	13,577	13,876	14,153	14,408	14,657
	Cost/Rx (£)		9,012	9,148	9,285	9,424	9,566	9,709	9,855	10,002	10,152	10,305	10,459	10,616	10,775	10,937
	Cost/Rx (\$)		12,546	12,735	12,926	13,120	13,316	13,516	13,719	13,925	14,133	14,345	14,561	14,779	15,001	15,226
	Sales (£)		12	30	53	77	95	108	119	129	134	140	145	150	155	160
	Sales (\$)		17	41	74	107	132	150	166	179	187	195	202	209	216	223
Total (Rx)		20,583	21,115	21,601	22,098	22,606	23,126	23,658	24,202	24,758	25,328	25,910	26,480	27,010	27,496	27,972
Total (\$MM)		345	339	346	350	355	363	373	384	397	412	427	443	459	474	489
Market shares based on TRx																
	Caelyx	70%	64%	56%	46%	38%	32%	29%	27%	26%	26%	26%	26%	26%	26%	26%
	Myocet	30%	30%	29%	28%	26%	25%	24%	23%	22%	22%	22%	22%	22%	22%	22%
	ATI-0918	0%	6%	15%	26%	36%	43%	47%	50%	52%	52%	52%	52%	52%	52%	52%
	Total	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Transfer revenue		1.8	4.5	8.2	11.7	14.6	16.5	18.3	19.7	20.6	21.4	22.2	23.0	23.8	24.5	
Royalties		3.3	8.3	14.9	21.4	26.5	30.1	33.2	35.9	37.4	39.0	40.4	41.8	43.2	44.6	
Total revenue to CYTX		5	13	23	33	41	47	51	56	58	60	63	65	67	69	

Source: Laidlaw & Company estimates

Figure 4b: ATI-0918 in Europe revenue model



Source: Laidlaw & Company estimates

ATI-1123 would be the next generic in the pipeline. In addition to ATI-0918, the nanomedicine division also has a second product, ATI-1123, also acquired from Azaya, in development. ATI-1123 is a liposomal formulation of docetaxel. Docetaxel has been approved for multiple cancer indications, including non-small cell lung, breast, head and neck, gastric and hormone refractory prostate cancers. Peak annual sales of the branded product, Taxotere, were €2.1 billion in 2010 and patent of Taxotere has expired in multiple countries. ATI-1123 has demonstrated better efficacy vs. docetaxel from preclinical studies. A Phase I dose-finding trial (n=29) showed ATI-1123 achieved a 20% increase in MTD vs. standard docetaxel. The study also showed 62% (16/26) stable disease with equivalent or improved safety vs. docetaxel. CYTX is evaluating the potential indications for possible Phase II studies and partnership prospect for future development.

Anticipated milestones in 2018 and beyond

Program	Indication	Event	Timing	Importance
Habe cell therapy	Scleroderma	FDA discussion regarding the potential next step for the U.S. clinical path	1H18	****
		Potentially report SCLERADEC-II study result	2H18	***
	Urinary Incontinence	Potentially complete patient enrollment of ADRESU study	1H18	***
		Potentially report ADRESU study result	2H18/2019	***
DCCT-10 therapeutic	Thermal Burn & Radiation Injury	Potentially start RELIEF study	1H18	***
ATI-0918	Generic liposomal doxorubicin in Europe	Start stability test	2Q18	***
		EMA filing	4Q18 or 2Q19	***
		EU Partnership	2018 / 2019	****
		Product launch	2020	****
	Generic liposomal doxorubicin in the U.S.	Potentially start bioequivalence study	2H18	***

**** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative

Source: Laidlaw & Company estimates and company presentation.

Financial Projections and Valuation

CYTX reported 3Q17 total cash of \$4.8MM and with an offering in 4Q17 of ~\$10MM, we estimate the company could have cash (pro forma) of approximately \$12MM. The total cash should support the company's operations through 2018, by our estimate.

We have employed a probability-adjusted cash flow-based sum-of-the-part analysis with a \$1.67 fair value which mainly accounts for the NPV of cash from 1) ATI-0918 European royalty revenues; 2) potential Habeo cell therapy approved uses in the U.S. 3) potential sales from Celution system from approved and potentially more claim expansion from Japan and possibly other territories and 4) possible cash by early 2019. As such, we derive a Buy rating and one-year target price of **\$1.65** for CYTX shares.

NPV driven sum-of-the-part analysis

ATI-0918 Oncology		
	Total NPV = 107	
	Probability adjustment = 43%	
	Risk-adjusted total NPV = 45.9	
	Value per share =	\$1.17 70%
Habeo cell therapy		
	Total NPV = 30	
	Probability adjustment = 15%	
	Risk-adjusted total NPV = 4.5	
	Value per share =	\$0.11 7%
Cytori Japan		
	Total NPV = 18	
	Probability adjustment = 28%	
	Risk-adjusted total NPV = 5.0	
	Value per share =	\$0.13 8%
Debt-free cash		
	Value in Early 2019 = 10	
	Value per share =	\$0.25 15%
	Total =	\$1.67 100%

Source: Laidlaw & Company estimates

Major Risks

Clinical risks of clinical study failure could have a major impact on CYTX share value. Despite encouraging earlier clinical study outcome in some indications, which potentially bodes well for a positive outlook of future studies, it remains too early to project the possible success of several ongoing investigator sponsored clinical trials. Given that the substantial upside potential for CYTX shares is currently based on the success of certain studies, a failed study outcome or/and an unsuccessful approval application would have a significant negative impact on CYTX share value.

Regulatory and/or commercial success of the ATI-0918 is less predictable. Although ATI-0918 has been shown to be bioequivalent to the reference drug, Caelyx, it might be difficult to project with greater precision on the success of EMA approval and European partnership with favorable term to CYTX. Even ATI-0918 is launched in Europe, it might be still difficult to project, with greater precision, the future sales growth from the European markets. Should the sales performance in Europe be less successful than expected, CYTX share value could be negatively impacted.

Lack of sufficient cash could impede corporate development. With additional financial needs to support clinical studies and other operating expenses going forward, the company might have to raise additional capital via either financial market or non-dilutive sources to advance its pipeline development. Given it is possible that costs for some of the pivotal studies could be very substantial due to sizeable studies, the company might much prefer to find non-dilutive financial sources for moving the program forward. It is possible by raising capital at a less favorable term; CYTX's share price could decline.

Risks from international exposure. A substantial portion of CYTX's current revenues are derived from sales outside the U.S., especially from the European and Asia-Pacific regions. As such, the company is exposed to potential risks of currency fluctuations, as well as pricing controls, regulatory requirements and reimbursement practices that differ from that of the U.S.

Management

Marc H. Hedrick, M.D. has served as CEO since 2014 of Cytori Therapeutics and President since May 2004 after he has served as Chief Scientific Officer, Medical Director and Director since October 2002. Prior to joining Cytori, he co-founded, and served as President and Chief Executive Officer of StemSource, Inc. Previously, he served as Associate Professor of Surgery and Pediatrics at the University of California, Los Angeles (UCLA) from 1998 until 2005, and directed the Laboratory of Regenerative Bioengineering and Repair for the Department of Surgery at UCLA. Dr. Hedrick holds M.D. from the University of Texas Southwestern Medical School, Dallas and an MBA from UCLA.

Tiago Girão has served as CFO of Cytori Therapeutics since 2014. Prior to joining Cytori, Mr. Girão served as International Controller from February to August 2014 and as Director of Financial Reporting since 2012 of NuVasive. Prior to joining NuVasive, Mr. Girão held the position of Senior Manager, Assurance at KPMG, LLP since 2004. Prior to joining KPMG, Mr. Girão was a senior accountant for Ernst & Young in Brazil since 2000. Mr. Girão holds a B.A. from University of Fortaleza in Brazil.

John D. Harris has served as VP and General Manager of Cell Therapy of Cytori Therapeutics since 2015. Prior to joining Cytori, Mr. Harris served as Vice President and General Manager of Becton Dickinson's operations in Japan. Previously, Mr. Harris held business development, product development, and marketing and sales leadership roles with Tyco Electronics. Mr. Harris holds a MBA from University of Utah.

Mark Marino, M.D. served as Senior VP of Medical Affairs, and was also appointed as Chief Medical Officer of Cytori Therapeutics since 2016. Prior to joining Cytori, Dr. Marino served as Senior VP of Early Clinical Development for Turing Pharmaceuticals since 2015. Prior to Turing, Dr. Marino served as Executive Director of Clinical Development, and before, as VP of Clinical Development at Daiichi-Sankyo since 2012. Prior to Daiichi-Sankyo, Dr. Marino held various senior clinical positions at Archimedes Pharma, Inc., MannKind Corporation and Hoffman-LaRoche since 2006. Prior, he also served as Chief of the Department of Pharmacology at the Walter Reed Army Institute of Research as well as Associate Professor of Medicine at the Uniformed Services University of the Health Sciences and a staff physician at the Walter Reed Army Medical Center. Dr. Marino holds a MD from the Albert Einstein School of Medicine.

Jeremy B. Hayden has served as VP of Business Development of Cytori Therapeutics since 2015. Prior to joining Cytori, Mr. Hayden served as Assistant General Counsel at Volcano Corporation. Previously, Mr. Hayden practiced corporate and securities law at several national and international law firms. Mr. Hayden holds a J.D. from the University of Michigan Law School.

Figure 1: Income Statement

Cytori Therapeutics, Inc. – Income Statement														
(’000 \$)	2015	2016	1Q17	2Q17	3Q17	4Q17E	2017	1Q18E	2Q18E	3Q18E	4Q18E	2018E	2019E	2020E
Product revenues	4,838	4,656	591	969	467	600	2,627	642	693	721	748	2,804	3,786	5,073
ATI-0918 revenue														5,191
Amortization of intangible assets			306	306	306	306	1,224	306	306	306	306	1,224	1,261	1,299
Product revenues	4,838	4,656	897	1,275	773	906	3,851	948	999	1,027	1,054	4,028	5,046	11,563
Government contracts and other	6,821	6,724	1,018	531	1,306	1,211	4,066	1,167	1,864	2,011	2,109	7,151	7,437	7,735
Development revenues	6,821	6,724	1,018	531	1,306	1,211	4,066	1,167	1,864	2,011	2,109	7,151	7,437	7,735
Total Revenue	11,659	11,380	1,915	1,806	2,079	2,117	7,917	2,115	2,863	3,038	3,163	11,179	12,483	19,297
Cost of product revenues	3,186	2,715	410	401	181	250	1,242	302	326	339	351	1,318	1,779	4,059
Gross profit	1,652	1,941	(125)	262	(20)	44	161	34	61	76	90	262	746	4,907
Research and development	19,000	16,197	3,289	2,992	3,004	3,100	12,385	3,131	3,137	3,200	3,264	12,732	13,331	13,957
Sales and marketing	2,662	3,611	939	1,263	840	900	3,942	909	918	927	937	3,691	3,802	3,916
General and administrative	9,765	8,563	2,108	2,119	1,785	1,829	7,841	1,847	1,857	1,866	1,875	7,445	7,966	8,524
In process research and development acquired from Azaya Therapeutics			1,686				1,686							
Change in fair value of warrant liability	(7,668)													
Operating expense	23,759	28,371	8,022	6,374	5,629	5,829	25,854	5,887	5,912	5,993	6,076	23,868	25,098	26,396
Operating income	(15,286)	(19,706)	(7,129)	(5,581)	(4,343)	(4,574)	(21,627)	(4,686)	(3,986)	(3,966)	(3,876)	(16,455)	(16,915)	(13,755)
Interest income	9	19	11	7	5	9	32	7	9	11	8	35	40	41
Interest expense	(3,379)	(2,592)	(591)	(538)	(474)	(488)	(2,091)	(510)	(532)	(495)	(476)	(2,013)	(2,100)	(2,200)
Other income (expense), net	(88)	233	165	63	5	10	243	15	99	21	34	169	186	189
Total other income (expense)	(3,458)	(2,340)	(415)	(468)	(464)	(469)	(1,816)	(488)	(424)	(463)	(434)	(1,809)	(1,874)	(1,970)
Income (loss) before taxes	(18,744)	(22,046)	(7,544)	(6,049)	(4,807)	(5,043)	(23,443)	(5,174)	(4,410)	(4,369)	(4,310)	(18,264)	(18,789)	(15,725)
Income tax expense	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net income	(18,744)	(22,046)	(7,544)	(6,049)	(4,807)	(5,043)	(23,443)	(5,174)	(4,410)	(4,369)	(4,310)	(18,264)	(18,789)	(15,725)
Net income attributable to common shareholders	(\$19,405)	(\$22,046)	(\$7,544)	(\$6,049)	(\$4,807)	(\$5,043)	(\$23,443)	(\$5,174)	(\$4,410)	(\$4,369)	(\$4,310)	(\$18,264)	(\$18,789)	(\$15,725)
Net Earnings (Losses) Per Share—Basic	(\$0.14)	(\$1.28)	(\$0.33)	(\$0.19)	(\$0.14)	(\$0.14)	(\$0.76)	(\$0.14)	(\$0.12)	(\$0.11)	(\$0.11)	(\$0.48)	(\$0.46)	(\$0.37)
Net Earnings (Losses) Per Share—Diluted	(\$0.14)	(\$1.28)	(\$0.33)	(\$0.19)	(\$0.14)	(\$0.14)	(\$0.76)	(\$0.14)	(\$0.12)	(\$0.11)	(\$0.11)	(\$0.48)	(\$0.46)	(\$0.37)
Shares outstanding—basic	140,797	17,291	22,736	31,251	34,491	35,291	30,942	36,291	37,291	38,291	39,291	37,791	40,791	42,791
Shares outstanding—diluted	140,797	17,291	22,736	31,251	34,491	35,291	30,942	36,291	37,291	38,291	39,291	37,791	40,791	42,791
Margin Analysis (% of Sales/Revenue)														
COGS	66%	58%	69%	41%	39%	42%	47%	47%	47%	47%	47%	47%	47%	47%
R&D	163%	142%	172%	166%	144%	146%	156%	148%	110%	105%	103%	114%	107%	72%
S&M	55%	78%	49%	70%	40%	43%	102%	43%	32%	31%	30%	92%	30%	20%
G&A	84%	75%	110%	117%	86%	86%	99%	87%	65%	61%	59%	67%	64%	44%
Operating Income (loss)	-131%	-173%	-372%	-309%	-209%	-216%	-273%	-222%	-139%	-129%	-123%	-147%	-136%	-71%
Pretax	-161%	-194%	-394%	-335%	-231%	-238%	-296%	-245%	-154%	-144%	-136%	-163%	-151%	-81%
Tax Rate	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Net Income	-161%	-194%	-394%	-335%	-231%	-238%	-296%	-245%	-154%	-144%	-136%	-163%	-151%	-81%
Financial Indicator Growth Analysis (YoY%)														
Product revenues	-2%	-4%	-37%	6%	-2%	-38%	-17%	6%	-22%	33%	16%	5%	25%	129%
Government contracts and other	158%	-1%	-36%	-69%	-30%	-22%	-40%	15%	251%	54%	74%	76%	4%	4%
Total Revenue	53%	-2%	-54%	-85%	-31%	-27%	-30%	-30%	-75%	59%	75%	41%	12%	55%
Cost of goods sold	8%	-15%	N.A.	-87%	-64%	-79%	-54%	N.A.	-88%	-15%	41%	6%	35%	128%
R&D expenses	26%	-15%	-20%	-43%	-24%	8%	-24%	-5%	5%	7%	5%	3%	5%	5%
Sales and marketing	-58%	36%	-9%	42%	3%	4%	9%	-3%	-27%	10%	4%	-6%	3%	3%
G&A	-39%	-12%	-8%	-9%	-11%	-6%	-8%	-12%	-12%	5%	3%	-5%	7%	7%
Operating expense	-36%	19%	8%	-25%	-17%	3%	-9%	-27%	-7%	6%	4%	-8%	5%	5%
Operating Incomes (Losses)	-53%	29%	40%	-10%	-9%	20%	10%	-34%	-29%	-10%	-15%	-24%	3%	-19%
Pretax Income	-50%	18%	41%	-6%	-11%	-2%	6%	-31%	-27%	-9%	-15%	-22%	3%	-16%
Net Income	-51%	18%	41%	-6%	-11%	-2%	6%	-31%	-27%	-9%	-15%	-22%	3%	-16%
EPS - Basic	-70%	791%	-19%	-55%	-47%	-42%	-41%	-57%	-39%	-18%	-23%	-36%	-5%	-20%
EPS - Diluted	-70%	791%	-19%	-55%	-47%	-42%	-41%	-57%	-39%	-18%	-23%	-36%	-5%	-20%

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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates.

DISCLOSURES:

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Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price (\$)
11/19/...	Drop (D)	5.10
02/22/...	Buy (B)	0.32*

3 Year Price Change History

Date	Target Price (\$)	Closing Price (\$)
11/19/...		5.10
02/22/...	1.65	0.32*

* Previous Close 2/20/2018

Source: Laidlaw & Company

Created by: Blue-Compass.net

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	69.23%	28.85%	3.85%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	1.92%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

Johnson and Johnson (JNJ: Not Rated)
 Teva (TEVA: Not Rated)
 CytRx (CYTR: Not Rated)
 Sun Pharma (SUNP IN: Not Rated)
 Taiwan Liposome Company (4152.TWO: Not Rated)

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NOTES: