ENCODE

IDEAS

COVERAGE LIST UPDATE

TLC | DCTH | ECX.DE | ESSA | XENE | ACST

July 26, 2020

Since our last update note in January, we have initiated on three new companies; TLC (Nasdaq: TLC), Delcath Systems (Nasdaq: DCTH), and Epigenomics (FSE: ECX.DE, OTC: EPGNF). This brings our total coverage universe to six companies. As we have highlighted previously, after we issue our initiation reports, we generally will not issue follow-on reports. We will on occasion issue these update letters, but for our most timely commentary, we recommend you follow us on Twitter (@encodelp).

TLC (Nasdaq: TLC) Initiated 04/27/20 @ $4.25

TLC has been busy since our initiation report. They announced top-line Ph2 data for TLC590 in postoperative pain, raised $35mm in equity and debt ($23mm equity / $12mm debt), and just a few weeks ago, provided some preclinical data on a potential inhaled liposomal formulation of hydroxychloroquine (HCQ) for COVID-19.

Let's start with the COVID-19 news first. As we highlighted in our initiation report, TLC are experts in liposomal drug delivery. They have two liposomal reformulations approved in Taiwan, and their founder and CEO Keelung Hong, was co-inventor of FDA-approved Onivyde, a liposomal formulation of irinotecan, while at Hermes Biosciences. The company has presented some early data suggesting an inhalable liposomal formulation of HCQ had a 30x increase in lung exposure versus oral HCQ while also achieving lower systemic exposure. The benefit, or lack thereof, of HCQ to manage COVID-19 infections, is clearly a polarizing topic in medicine (and politics) right now, but one the biggest concerns is the product's safety profile. In June FDA revoked the emergency use authorization for HCQ stating, "...in light of ongoing serious cardiac adverse events and other potential serious side effects, the known and potential benefits of chloroquine and hydroxychloroquine no longer outweigh the known and potential risks for the authorized use." TLC's hypothesis is that inhaled liposomal HCQ can achieve sufficient and locally sustained drug exposure in the lungs at a tiny fraction of the oral dose, while also reducing the systemic and cardiac toxicities commonly seen with oral HCQ. TLC has not announced any formal development plans for its HCQ formulation, but we suspect that news is imminent.

We would not be surprised if TLC were experimenting with liposomal formulations of other investigative therapies for COVID-19. It is worth noting that their most advanced development stage product is a liposomal formulation of dexamethasone, TLC599, for the treatment of osteoarthritis (OA) of the knee. Recent data from the UK, published in NEJM, found dexamethasone treatment had a mortality benefit in the treatment of hospitalized COVID-19 patients. TLC's development of liposomal dexamethasone for COVID-19 is pure speculation on our part, but given their knowledge of the drug through the development of TLC599, and recent interest in liposomal HCQ, it is within the realm of possibility in our opinion.

At the end of May, TLC announced top-line data from their Ph2 bunionectomy study with their liposomal formulation of ropivacaine, TLC590. TLC590 was numerically superior to placebo and standard of care bupivacaine on pain intensity scores across all time periods through to 168 hours, but was not statistically superior at the predefined primary endpoint of pain score at 72 hours (AUC 0-72). Interestingly TLC590 did demonstrate a statistically significant improvement in pain scores at 24 hours (AUC 0-24) versus placebo and bupivacaine. Given the small sample size (150 patients / 3 arms), we feel these data are positive, and when combined with the earlier Ph2 data in hernia repair, provide ample evidence to advance TLC590 into either a larger

Ph2b study, or potentially directly into a Ph3 program. We feel TLC will likely take the more aggressive approach and push right into Ph3 with TLC590. Part of the company's motivation to push into Ph3 could be the recent FDA setback experienced by their postoperative pain peer / competitor, Heron Therapeutics (HRTX). Heron recently received its second complete response letter from FDA for HTX-011, their extended-release formulation of bupivacaine in combination with meloxicam, which arguably narrows the development gap between TLC and Heron. We anticipate more data disclosure from the bunionectomy study from TLC soon, and likely an update on their future development plans at the same time.

The company topped up its balance sheet in June with some equity, $23mm (5m shares @ $4.60), and debt, $12mm. TLC has stated that this cash gives them sufficient runway beyond their Ph3 top-line data release for their liposomal formulation of dexamethasone, TLC599, in OA of the knee, currently guided to be 4Q21.

TLC should be "news-rich" over the coming weeks and months, with likely disclosures around their COVID-19 development plans for inhaled HCQ, additional data from Ph2 bunionectomy study with TLC590, and potentially preliminary Ph1 data from TLC178, their liposomal formulation of the chemotherapy vinorelbine. The recent COVID-19 news temporarily catapulted the stock north of $10 and triggered some much-needed liquidity in this historically thin trader, but as we write this, the stock appears to be settling in around $6. We think at these levels TLC is very affordable given the impending newsflow and mid/late-stage pipeline with TLC590 and TLC599.

Delcath Systems (Nasdaq: DCTH) Initiated 05/06/20 @ $7.45

As we stated in our initiation report, we believe Delcath's current ~$60mm valuation reflects its "colorful past and not its bright future". Over the past months, the company has continued to expunge that colorful past with a series of leadership changes. The board has been almost completely turned over, with four new members, including two from the company's largest shareholder, Rosalind Advisors. The company's legacy CEO and CFO are gone, and John Purpura has assumed the role of interim-CEO, as the board engages in an active leadership search. We have spoken with John Purpura a number of times, and are very confident he can navigate the company for the foreseeable future, as the board engages in its leadership search.

Delcath has sharpened its guidance on the timing of top-line data from the Ph3 registrational FOCUS study in metastatic ocular melanoma (mOM) to 4Q20. Pre-COVID these data were expected mid-20, so this is only a slight push on timelines. We continue to be highly optimistic about a positive outcome for the Ph3 FOCUS study later this year.

We are also expecting an update on the company's Ph3 ALIGN study in Intrahepatic cholangiocarcinoma (ICC). This study has been paused while Delcath discusses protocol amendments with FDA. The company has guided that they should have FDA feedback this quarter and re-start the study in 4Q20.

The company has a new presentation available on its website, that we recommend investors review. In it, they present new mOM U.S. incidence numbers which indicate a bigger addressable patient population of 1,530 annually, where we were estimating 1,000. This would make the U.S. addressable market in mOM over $300mm annually based on $200k / treatment with Delcath's hepatic delivery system (HDS). The presentation also includes some preliminary market research, including a survey of oncologists where, " A majority of oncologists we surveyed believe that up to 80% of their mOM patients with liver metastases would be candidates for treatment with Melphalan/HDS due to its clinical benefits and safety profile".

Delcath is fully funded through its Ph3 FOCUS readout later this year, and for a likely NDA submission 1H21. The company also has ~4mm $10 warrants outstanding and with the recent stock action, we could see some of these warrants exercised, further extending the company's financial runway.

Epigenomics (Germany: ECX, OTC: EPGNF) Initiated 06/17/20 @ $1.32

Our most recent initiation Epigenomics, also has the most imminent catalyst, with a huge CMS reimbursement decision on, or before, August 28th. We believe the company has checked all the boxes to achieve CMS reimbursement for Epi proColon; FDA PMA approval, inclusion on CMS rate schedule, completion and publication of microsimulation study, and recent inclusion in the 2020 NCCN colorectal cancer guidelines. During the 30-day public commentary period for the CMS National Coverage Decision (NCD), >95% of the comments came in favor of reimbursement for Epi proColon. We highlight a few of the notable public comments from the NCD;

Holly Anderson, Executive Director, Colon Cancer Coalition, "...A simple blood test available in a doctor's office may go a long way to screening at risk or other vulnerable populations covered through Medicare…"

Michael Sapienza, CEO, Colorectal Cancer Alliance "...The best colorectal cancer screening test recommended by the Colorectal Cancer Alliance is the test "that gets done". For that reason, we believe that CMS should cover all FDA approved screening methods in order to maximize compliance adherence to colorectal cancer screening guidelines…"

We are hosting a Virtual 1x1 Webinar with Epigenomics AG senior management; Greg Hamilton, CEO, and Jorge Garces, PhD, President and Chief Scientific Officer, on Tuesday, July 28th at 10:30 AM ET. Please visit our website to register for this event.

ESSA (Nasdaq: EPIX) Initiated 11/11/19 @ $4.30

ESSA has begun its Ph1 study with EPI-7386, its N-terminal domain antagonist, in men with metastatic castration resistant prostate cancer (mCRPC). The company recently announced the first patient enrolled in the study, and we are budgeting for preliminary data 1Q20. Investors should be closely watching the PSA results from this study, and compare them against those recently generated by ESSA peers Arvinas (ARVN) and MacroGenics (MGNX). Both companies reported Ph1 data in heavily pretreated men with mCRPC at ASCO in May. In the case of Arvinas the results were underwhelming with only 2 of 7 men experiencing >50% reduction in PSA with ARV-110 and this only included the patients from the higher dose cohorts. There was also some concerning safety issues, with potential drug-drug interaction with a commonly prescribed statin. MacroGenics on the other hand, reported data across all dosing cohorts of MGC018, with an impressive 5 of 7 men experiencing >50% reduction in PSA. Both Macrogenics and Arvinas carry ~$1.3B market caps, but in fairness, they are both more traditional pipeline plays, whereas ESSA is a single-asset pure-play mCRPC company. Even with this in mind, we feel at ~$200mm market cap, ESSA has tremendous upside if it can deliver positive PSA results from their Ph1 mCRPC study in early 2021.

Xenon (Nasdaq: XENE) Initiated 10/16/19 @ $8.35

As we have commented on Twitter, we feel Xenon could be range-bound for the foreseeable future. We love the epilepsy pipeline, but the key catalyst we were anticipating this year, data from the Ph2b focal seizure study with XEN1101, has been pushed into 1H21 due to COVID-19, muting the urgency to own the stock today. The company should have a number of milestones in the near-term, including; their partner Neurocrine (NBIX) filing an IND for XEN901, triggering a $25mm payment to Xenon, initiation of the pivotal Ph3 study with XEN496 in the ultra-rare KCNQ2 infantile epilepsy disorder, and possibly Ph2 data from a small physician initiated study in childhood absence epilepsy with XEN007. We believe these milestones will add incremental value to Xenon, but in our opinion, none are likely to push the stock out of its current $11-$15 range.

Having thrown cold water on Xenon as a near-term catalyst investment, we can make a compelling argument for Xenon as a value investment here. With a market cap of $450mm, and cash of $230mm (03/31/20), in our opinion, the company has a modest enterprise value for a late-stage CNS company. We believe both their late-stage Kv7 assets, XEN1101 and XEN496, have a good chance for clinical success, given the proven antiepileptic benefit of targeting the Kv7 channel with FDA-approved ezogabine. We stated in an earlier update report that "...2020 is the year where Xenon closes the valuation gap with its later-stage CNS peers, Sage (SAGE), Axsome (AXSM), and Zogenix (ZGNX)." We still believe this to be the case, but suspect 2021 is the year where the valuation gap begins to close.

Acasti (ACST) Initiated 11/25/19 @ $2.04

We have decided to no longer actively cover Acasti. Given our knowledge on the name, we may make comments on Twitter from time-to-time, but will no longer include them in these update notes. With that in mind, we will provide some final thoughts on the company.

As a reminder, we initiated on Acasti in advance of their first Ph3 Trilogy readout. In our report, we recommended caution to investors heading into Trilogy 1, suggesting that staying on the sidelines for the top-line data release was the best strategy. As we now head into the Trilogy 2 readout, we would once again emphatically recommend caution to investors. Acasti has reported data for CaPre in two Ph2 studies (COLT & Trifecta) and one Ph3 study (Trilogy 1), none of which give us confidence in a favorable outcome for Trilogy 2. Even in a scenario where CaPre hits the primary triglyceride-lowering endpoint in Trilogy 2,

they will almost certainly have to run another Ph3 study for an NDA submission. The stock could have one last speculative run into top-line Trilogy 2, but holding through this event is very high-risk in our opinion.

Other Names of Interest

We thought we would throw out a few other names that are not actively covered by Encode, but are potential research names, or simply companies we own and like.

Aerpio (Nasdaq: ARPO): For ~$60mm cap / $45mm cash / $15mm EV, you get Ph2 glaucoma asset with data in next 3-6 months, Ph2 therapeutic COVID-19 program supported by I-SPY due to kick off soon, and Gossamer (GOSS) partnership.

Perimeter Medical Imaging AI (TSX-V: PINK): 510(k) cleared intraoperative imaging technology for detecting +ve margins during lumpectomies, pursuing additional 510(k) for AI, large reimbursement study starting soon, $7M CPRIT funding, recent RTO onto TSX-V, U.S.-listing in fall.

Affimed (NASDAQ: AFMD) ~$315mm / 100M cash+, investors should see Ph1 data with AFM24 in EGFR+ solid tumors this year, Roche moving AFM26 forward and potential milestones, and MD Anderson recruiting for the combo study of cbNK + AFM13

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