ENCODE
IDEAS

COVERAGE LIST UPDATE

DCTH | XENE | OCUP | TLC | PINK | PCSA | EPGNF | EPIX

March 7, 2021

We thought it timely to provide an update on our coverage universe. Many of our names have imminent catalysts that warrant investors' attention. We also have two names that we are going to retire from active coverage, one was a big win, the other…….. wasn't.

Let's start by reviewing our active coverage list as it stands today. Below is a quick snapshot of our research universe. We are very pleased with the performance of the broader research portfolio.

Company	Ticker	Initiation Date	Initiation Price	Current Price	% Change
Xenon Pharmaceuticals	XENE	10/16/19	$8.35	$19.92	*138.56%*
ESSA Pharma	EPIX	11/11/19	$4.30	$27.06	*529.30%*
TLC	TLC	04/27/20	$4.25	$4.93	*16.00%*
Delcath Systems	DCTH	05/19/20	$7.35	$17.91	*143.67%*
Epigenomics	EPGNF*	06/17/20	$1.32	$0.32	*-75.28%*
Perimeter Medical Imaging	PINK.V**	10/21/20	$2.02	$4.05	*100%*
Ocuphire Pharma	OCUP	11/09/20	$6.14	$9.36	*52.44%*
Processa Pharma	PCSA	2/22/21	$10.89	$10.77	*-1.10%*

*EPGNF current price is calculated based on 8:1 consolidation
**PINK.V prices are in CAD

Average Return **112.95%**

Delcath Systems (Nasdaq: DCTH) Initiated 05/19/20 @ $7.35

We, like many Delcath investors, were hoping to see top-line Ph3 FOCUS data by now, but based on the most recent guidance from the company at the February BTIG Medtech Conference, it looks like data will be late-March or April. The delay in top-line data is not concerning to us. CEO Michel has been forthcoming that the delay is a monitoring and site access issue caused by COVID-19 and that data integrity remains intact. During the BTIG presentation, Michel guided on his expectations for PHP efficacy in mOM for many of the FOCUS endpoints, including ORR (>27% seen in 1st Ph3 study), DCR (80-90% similar to data generated in the EU), and OS (15-18 months similar to data generated in the EU, and PHP>BAC). Based on this efficacy guidance, the reiteration of the improved safety profile seen thus far in FOCUS, and the abundance of historical data, we are very confident Delcath will report positive Ph3 data in the coming weeks. Beyond top-line data in March/April, we expect Delcath will be news-rich throughout 2021, with additional data releases from FOCUS and indication expansion / new trial initiations over the coming months.

We highly recommend investors interested in Delcath watch the BTIG presentation (link below) before it expires

DCTH BTIG Presentation

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

Xenon's long data drought is almost over, with top-line Ph2b X-TOLE data for XEN1101 expected 3Q21. The outcome of this large RCT in patients with focal epilepsy will be defining for Xenon. We believe XEN1101 has an excellent chance of success in X-TOLE, given its a next-gen Kv7 agonist built off the same scaffold as FDA-approved AED ezogabine and the positive pharmacodynamic TMS data generated in their Ph1b study. Xenon also recently announced its plans to develop XEN1101 for MDD. This decision was based on some fantastic placebo-controlled data generated, in a very small sample size (n=45), from Mount Sinai with ezogabine in MDD patients where statistically significant improvements are achieved across two depression scales vs placebo. Xenon is planning to initiate a Ph2 MDD study with XEN1101 later this year. We are also expecting more data from XEN007 in CAE 2H21, which we would expect to be incrementally positive. Lastly Xenon has (finally) begun enrolling in the Ph3 EPIK study with XEN496. The company has not provided guidance on timing of top-line data, but we assume, given the rarity of KCNQ2 epilepsy, that this study will enroll slowly, so we're budgeting for 2023 data.

We highly recommend investors interested in Xenon flip through their recent deck presented at ASENT in February (link below) on the Kv7 channel and its potential in the treatment of MDD. This deck includes a few slides on the Sinai data referenced above.
ASENT MDD Kv7 Deck

Ocuphire Pharma (Nasdaq: OCUP) Initiated 11/09/20 @ $6.14

Our launch on Ocuphire was somewhat clouded by the structured nature of the PIPE financing done concurrently with their RTO, and the temporary overhang it caused for the stock on its first days of trading. The price protection / reset provisions afforded to the financing participants over the first 10-days of trading, caused the stock to temporarily swoon below $5. Once the initial reset provisions had expired after 10-days of trading, the stock made a healthy recovery. Ocuphire management has subsequently negotiated the elimination of the remaining price protection / reset provisions afforded to the PIPE participants, leaving them with a clean cap structure heading into several big clinical catalysts.

With our crash course in structured financing behind us, we turn our attention towards Ocuphire''s plethora of clinical trials, one of which is due to report top-line data this month. Ocuphire has guided that they will report top-line data from their Ph3 MIRA-2 study evaluating Nyxol for the reveral of mydriasis (RM) before quarter's end. Although RM is the smallest of the three indications being pursued by Ocuphire, we believe the MIRA-2 data are arguably the most important of the ongoing studies with Nyxol. Success in RM should create a "halo effect" (no NVD pun intended) for the remaining two indications, NVD and presbyopia, instilling confidence in investors that Nyxol is behaving as expected, as a moderate and well tolerated miotic. Success in RM also puts a floor in Ocuphire's valuation, providing investors comfort that, irrespective of what happens in NVD and presbyopia, Nyxol's path to commercialization is one step closer. Of course we need to also consider the other side of the data coin, if a "halo effect" comes from positive data, negative data can cause a "contagion effect" for the two remaining indications. Fortunately we believe the probability of a negative outcome for Nyxol in RM is relatively low. Their earlier Ph2 MIRA-1 study clearly demonstrated Nyxol's ability to quickly return patients to within their baseline pupil diameter. The ongoing Ph3 MIRA-2 is a much larger study (4-5x Ph2) - well powered to demonstrate Nyxol's superiority vs placebo in RM. After RM, Ocuphire will report Ph2 data in presbyopia in 2Q21, followed by Ph3 NVD data in 3Q21, and cap their year off with data from their other pipeline product APX3330 in a Ph2 DME/DR study.

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

Within our coverage universe, TLC has been the most vexing. We like their two lead assets, TLC599 (knee OA) and TLC590 (post-up pain). TLC has generated good PoC data for both of these injectable liposomal assets. TLC is following the clinical playbook established by their commercial peers; Flexion's Zilretta for TLC599 and Pacira's Exparel for TLC590. Finally, both assets appear to have competitive advantages versus their commercial peers. However, TLC's 2020 was not defined by their encouraging Ph2 bunionectomy data with TLC590 or their impressive pace of enrolment in the Ph3 knee OA study with TLC599, instead it was defined by a preclinical paper published in a relatively obscure medical journal. These preclinical data were

pertaining to an inhalable liposomal formulation of HCQ. The story writes itself from there, TLC becomes a COVID-19 story, fast-money floods into the name, stock temporarily runs to >$10, only to make a quick round-trip back to its normal $5 range. For those of us focused on the company's core pain assets, this COVID noise was nothing but a distraction for much of 2020. TLC has subsequently spunout their inhalable portfolio, including the HCQ asset, into a well funded subsidiary, allowing investors to focus on the real value creating late-stage assets in their portfolio.

The big catalyst for TLC in 2021 will be top-line data from their Ph3 EXCELLENCE study evaluating TLC599 for knee OA by year-end. TLC599 appears to have several advantages over market incumbent Zilretta, including; (1) 6-month durability (2) multiple injections without cartilage deterioration (3) ability to expand beyond knee to smaller joints - shoulder and hip. In our opinion TLC599 has best-in-class potential, but first needs to conclusively demonstrate its efficacy in EXCELLENCE. Given the encouraging PoC data generated already with TLC599, we are optimistic in a positive outcome in EXCELLENCE, with the notable caveat that pain studies are notoriously difficult. In the meantime, we should also be learning about the Ph3 development plans for TLC590 in post-op pain after an upcoming EOP2 meeting with FDA.

Perimeter Medical Imaging (TSX-V: PINK) Initiated 10/21/21 @ CAD $2.02

Perimeter has been relatively quiet since our October 2020 launch, at least until last week, when they announced the 510(k) clearance for their go-to-market version of OTIS. Although we caution investors from focusing on the income statement at this stage, the commercial push for Perimeter has begun. We will be watching for news on OTIS installations at leading breast cancer surgery institutions throughout the year. In our opinion, investors should focus on the "where" and "who" as it pertains to OTIS sales, not the "how much" at this stage. We also expect news throughout the year on the development of Perimeter's AI plug-in for OTIS, ImgAssist. The company should be reporting data from their reader study shortly, and pivoting into a RCT. OTIS alone should be an attractive commercial business, but OTIS with ImgAssist could be a game changer.

Processa Pharma (Nasdaq: PCSA) Initiated 2/22/21 @ $10.89

We launched on Processa only a few weeks ago, so there isn't anything new to report. We await the initiation of the Ph1b study with PCS6422 in combination with Xeloda in advanced GI cancer and the Ph2 study with PCS499 in NL shortly. We should see some data from both these programs 2H21.

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

At the beginning of this report, we mentioned we are retiring a couple names from active coverage, one a big winner, and the other less so. Meet the less so - Epigenomics. We were absolutely convinced Epigenomics would receive CMS reimbursement for Epi proColon, but we were wrong. The company recently consolidated its stock and raised approximately $5mm through a convertible bond offering. They have cash through 2021, giving them time to explore their strategic options. The company plans to appeal the NCD from CMS, but that is expected to be a 12-month process. Interestingly the other path to CMS reimbursement is through legislation, a path that has suddenly become more viable with the Democrats controlling congress. In fact, Epi proColon's reimbursement could become part of a much larger bill that could be in front of congress in the coming months. In parallel with their CMS efforts, Epigenomics is likely also considering an outright exit, passing the Epi proColon fight onto a better financed company. Although we remain optimistic that Epi proColon will eventually get CMS reimbursement, either through legislation or an appeal, we are cutting our losses. We navigated into the confusing, and politicized, world of CMS reimbursement, only to be humbled, lesson learned.

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

At the other end of the spectrum, we are retiring ESSA after a terrific run. We have been vocal in our enthusiasm for EPI-7386 and how its unique MOA could be an important breakthrough for the management of mCRPC. The stock surged into our first look at Ph1 data for EPI-7386, and that first look didn't disappoint, with one patient in the first cohort experiencing >50% PSA reduction, even though the dose of EPI-7386, 200mg, was thought be sub-therapeutic. ESSA will report data from additional dosing cohorts at upcoming medical meetings throughout the year. We remain very enthusiastic about the company, but with a market cap that now ends in a "b", we feel our time is better allocated looking for the next ESSA.

On Our Radar

Anyone following us on social media knows we are enthusiastic about microbiome stocks, in particular bacteriophage names. The two notable public bacteriophage companies are BioMx (PHGE) and Armata (ARMP). Both companies have phage cocktails in human trials. BioMx has studies ongoing in acne and IBD/PCS. Armata has a study ongoing in CF. We will be watching for data from all these programs throughout 2021. Of note, Armata was our 2021 choice in the popular biotech stock picking contest #biopick2021 on Twitter.

Vistagen (VTGN) is another name we like. Their on-demand nasal spray, PH94B, for Social Anxiety Disorder (SAD) had strong Ph2 data, and they recently announced that FDA was supportive of a Ph3 program following a very similar design. The stock has had an excellent run after raising $100mm from smart-money funds. The company will be initiating a number of studies, in addition to their Ph3 SAD, throughout 2021, but data readouts aren't until 2022.

Aerpio (ARPO) is a name we highlighted in an earlier update letter as an interesting "value" play. Since then the stock tanked off underwhelming Ph2 glaucoma data, but has made a healthy rebound of late as the company undergoes a strategic review. Although Aerpio's pipeline has stalled, with uncerntaity surrounding the future of razuprotafib in ocular disease and COVID, the company has a substantial amount of cash, $47.3mm (09/30/21) and a promising mid-stage asset, GB004, partnered with Gossamer (GOSS). With a market cap of ~$70mm, Aerpio definitely should have appeal as an RTO target.

We generally don't gravitate towards income statement names, but Myomo (MYO), a wearable robotics company pushing towards cash-flow breakeven, intrigues us. The company recently pre-announced record 4Q20 earnings, an early indication of their direct-billing model, and social media marketing efforts, are working. For a low-float name, it actually trades relatively well.

Business

On the business front we are always looking for new names to cover, or own, so please reach out with any suggestions.

We appreciate your interest and support,

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