




Coverage Universe Update

Encode Ideas Coverage Update

Xenon Pharmaceuticals, Inc.
Delcath Systems, Inc.
Ocuphire Pharma, Inc.
Processa Pharmaceuticals, Inc.
Perimeter Medical Imaging AI, Inc.
Modular Medical, Inc.
Taiwan Liposome Company, Ltd.

September 6, 2021

 @encodelp

We generally don't focus on the macro when writing our updates, but unfortunately, we can't dive into company-specific updates without spending a minute on the poor market sentiment around biotech, and specifically micro / small cap bios. The XBI is down ~5% YTD and >20% from its February highs. The negative biotech investment sentiment over the past 6-months is even more telling when you consider that the broader markets have been steadily increasing and making all-time highs. Fortunately over the past few weeks, as we have been working on this update, the biotech market appears to have found a bottom and has begun making a nice recovery. Nonetheless, as we review our various coverage names, one theme that runs through them all is how difficult the biotech market has been of late, especially for smaller names that are tenuously financed, which apparently is our sweet spot :)

Looking at our coverage universe, since our March update, we have added only one new name Modular Medical. We had planned to have at least one other new launch during the period but found ourselves distracted by the poor market sentiment and the need to focus on supporting our existing names. Nonetheless, we plan to launch on two new names shortly and perhaps have a third out before YE. We are also retiring a name from coverage, TLC, after it recently announced plans to be taken private by Woods Investment Company, Ltd.

Live Coverage Universe

Company	Ticker	Initiation Date	Initiation Price	Current Price	% Change
Xenon Pharma	XENE	10/16/19	\$8.35	\$18.20	117.96%
Delcath Systems	DCTH	05/19/20	\$7.35	\$9.87	34.29%
Perimeter Medical	PINK.V	10/21/20	\$2.02	\$2.55	26.24%
Ocuphire Pharma	OCUP	11/09/20	\$6.14	\$4.35	-29.15%
Processa Pharma	PCSA	02/22/21	\$10.89	\$6.62	-39.21%
Modular Medical	MODD	06/07/21	\$5.96	\$3.45	-42.11%

Average Return Live Names 11.33%

Retired Names

Company	Ticker	Initiation Date	Initiation Price	Price at Retirement	% Change
Essa Pharma	EPIX	11/11/19	\$4.30	\$27.06	529.30%
Epigenomics	EPGNF	06/17/20	\$1.32	\$0.39	-70.45%
TLC	TLC	04/27/20	\$4.25	\$7.20	69.41%

Average Return Retired Names 176.09%

Total Average Return 66.25%

Finally, we are planning on launching a podcast in the coming months, where we will have discussions biotech / medtech pubco execs, portfolio managers, and KOLs. Stay tuned for more details very soon.

Xenon (XENE) Initiated 10/16/19 @ \$8.35, Currently \$18.20

We start with Xenon, given it has the most imminent catalyst within our coverage universe. The company has guided they will report top-line data from their >300-patient Ph2b adult focal epilepsy study, X-TOLE, by the end of Sept or mid-Oct. To say these XEN1101 data will be defining for Xenon likely understates their importance. Xenon's clinical portfolio is almost entirely focused on the Kv7 mechanism (Ph3 KCNQ2-DEE with XEN496 & Ph2 MDD with XEN1101) so success or failure in X-TOLE could have substantial read-through for these other programs.

As we have highlighted in our initiation report and subsequent updates, there are many reasons to be optimistic about XEN1101's probability of success in Ph2b, including; (1) ezogabine (1st gen Kv7 opener) has demonstrated the validity of the Kv7 mechanism through Ph3 success, FDA approval, and real-world use (2) XEN1101 (2nd gen Kv7 opener) came out of the same lab at Valeant that discovered ezogabine (3) Ph1b TMS pharmacodynamic data appear to demonstrate that XEN1101 is active in the CNS and dampens neuroexcitation. We temper our enthusiasm by simply highlighting that XEN1101 is novel chemistry being tested for the first time in patients with epilepsy and although there is strong evidence as to why XEN1101, as a 2nd gen Kv7 opener, "should" be an effective anti-epileptic drug (AED), there is yet evidence to demonstrate that it is an effective AED.

We have been consistent in our belief that XEN1101 has a strong likelihood of success in X-TOLE, for all the reasons we outlined above. We would also note that if the data were exceptionally strong in X-TOLE there is a possibility, given the size of the study, that FDA would consider it one of the two pivotal studies necessary for approval. Even though we are enthusiastic about a positive outcome in X-TOLE, investors always need to also consider the repercussions of a negative outcome and how poor results in X-TOLE could cause collateral damage to investor confidence for XEN1101 in major depressive disorder and XEN496 in KCNQ2-DEE. Fortunately, Xenon has the balance sheet strength that should reassure investors that positive data will be properly rewarded, given the lack of an urgent need for additional capital.

Delcath (DCTH) Initiated 05/19/20 @ \$7.35, Currently \$9.87

Delcath reported preliminary data from their Ph3 FOCUS metastatic ocular melanoma (mOM) study at the end of March. The stock sold off sharply after the data and has yet to recover to pre-FOCUS levels. The data presented in March were strong in our opinion, with Hepzato demonstrating an objective response rate (ORR) of 29.2% in the intent-to-treat (ITT) population, meeting its primary endpoint by exceeding the pre-specified 21% ORR hurdle. Additional analysis showed impressive statistically significant improvements with Hepzato vs the control best alternative care (BAC) arm in ORR, disease control rate (DCR), and progression-free survival (PFS). The safety of Hepzato was in line with expectations from recent European studies, with no treatment-related deaths and all SAEs considered manageable. Delcath has guided that complete FOCUS data will be presented in October at a company-sponsored R&D day.

We believe the preliminary data from FOCUS are strong, but the sell-off on data and lethargic action since, have certainly raised questions and doubts in some investors' minds. We attribute the poor performance of Delcath post-preliminary FOCUS data to a few things. First, the ORR% for Hepzato, although easily exceeding the 21% pre-specified threshold, was lower than what many investors expected. A few single-center European studies had shown ORR of >40% for Hepzato, and although Delcath tried to calibrate investor expectations downwards from these lofty ORR%, many investors were expecting something more than the 29.2% reported. In fairness to Delcath, the 29.2% ORR included 10 patients who never received treatment, but had to be included for the ITT analysis. The ORR for the patients who did receive Hepzato treatment was 32.9%. Another factor that impacted the ORR% was the 12-week interval for confirmatory CT scans. Most single-arm studies using RECIST v1.1 would use a much shorter interval for confirmatory scans - as short as 4-weeks in some cases. The 12-week interval in FOCUS was in place from when the study was a randomized controlled trial (RCT) with OS as the primary endpoint. Given that ~60 patients had been treated under the original RCT protocol when they reached an agreement with FDA to move FOCUS to a single-arm design, they chose to keep the longer interval for confirmatory scans. It is conjecture at this stage, but a shorter interval would have likely resulted in a higher ORR% for Hepzato, an assumption arguably supported by the 44% best overall response (BoR) results for Hepzato, released at ASCO a few months after the preliminary data. Nonetheless, Delcath investors should feel encouraged that patients who responded were "deep" responders, which should translate into good durability of response (DoR) results which will be reported with the complete FOCUS dataset in October.

Another likely reason for the Delcath sell-off post FOCUS was perceived balance sheet weakness. Ironically at the end of 1Q21, when Delcath reported preliminary FOCUS data, their balance sheet was at its strongest position in close to a decade, having completed a \$22mm deal @ \$13.25 in late-20. Nonetheless, with a balance sheet still measured in months of runway (albeit ~18 months) and biotech in the grips of a nasty buyers strike, the liquidity from the preliminary FOCUS data presented a perfect opportunity for investors to sell the news, with an eye towards potentially being able to re-load on a future equity financing. The stock has yet to recover from the FOCUS sell-off, and with the XBI still in a funk (although showing signs of recovery of late), Delcath opted to raise money via debt in a recently announced \$20mm deal with Avenue Venture Opportunities. Delcath's balance sheet could still use bolstering, but the company has removed any urgent need for cash, and can safely see itself through some very important milestones, most notably complete FOCUS data in October and NDA resubmission in 1Q22.

We remain very enthusiastic about Delcath. In our opinion, the preliminary data reported from FOCUS were strong. The primary ORR endpoint has been met, and that will not change when the final data are presented in October. In fact, we expect Hepzato should push over the symbolic 30% ORR mark when the final 11 patients are included in the primary ITT analysis. The preliminary data for Hepzato vs BAC were excellent, with statistically significant improvements across all key reported endpoints. Of course, the one key endpoint that has yet to be reported

from FOCUS is survival. On the company's 4Q20 call CEO Michel stated that based on data to date, Hepzato was showing a 4-month survival benefit vs BAC. We believe the company will report positive survival data in October along the lines guided by CEO Michel (i.e. 4-month OS improvement for Hepzato vs BAC) but highlight that there could be upside if the OS separation is greater than what has been guided thus far.

Looking beyond final FOCUS data in October, we think Delcath will be a topical stock throughout 2022. We expect additional studies with Hepzato to be initiated in new indications (ICC and mCRC), NDA resubmission, likely FDA Adcom, and PDUFA date / FDA decision, all within the next 12-months. Delcath will always have its detractors, given its colorful history, so as it begins checking off its milestones in the coming months, we would expect a vibrant debate on Hepzato's "approvability" to occur, positioning Delcath to be one of the most topical micro / small cap biotech stocks in 2022.

Ocuphire (OCUP), Initiated 11/09/2020 @ 6.14, Currently \$4.35

Ocuphire has been very busy since our last update report in March, reporting results from two studies with Nyxol, first from their Ph3 reversal of mydriasis (RM) study late-Q1, followed by Ph2 presbyopia data late-Q2. In our earlier update, we stated that;

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.

Ocuphire's Ph3, MIRA-2, RM study was unambiguously positive in our opinion. The study achieved its primary endpoint with Nyxol demonstrating a statistically significant return to baseline pupil diameter at 90-minutes vs vehicle. Importantly, Nyxol also showed a clinically meaningful and statistically significant return to baseline vs vehicle at 60-minutes, something we highlighted in our initiation report as being a secondary endpoint of interest to FDA.

The positive MIRA-2 news, instead of putting a floor in Ocuphire's valuation as we predicted, precipitated further erosion in the company's share price. The stock was already in a tailspin heading into MIRA-2 data, likely caused by a combination of factors; the buyer's strike in biotech (see above), the company's vulnerable balance sheet (sell the news, again see above), and finally the unwinding of the company's earlier structured go-public RTO financing. The sell-off post-MIRA-2 could also be partly due to the RM indication, and investor uncertainty about the size and relevance of it as a consumer-driven Rx market. Although there is precedence for FDA approval in RM (Rev-Eyes in the 90s), the market dynamics (size, consumer interest, pricing dynamics) are unproven. Ocuphire has shared their market research, suggesting the market size for RM could be >\$325mm / year in the U.S., but frankly, we don't think

investors should get too distracted about what the RM market may or may not be at this stage. Rather we would focus on the fact that; (1) the unambiguously positive data from MIRA-2 are highly predictive of another positive outcome in the upcoming confirmatory Ph3 MIRA-3 study (2) success in MIRA-3 gives Nyxol a high probability of FDA approval in 2023 (3) if FDA approved Nyxol would be the only drug available for RM (4) the target patient population is huge, with >80mm eye exams performed annually in the U.S.

In our opinion, Nyxol is a real drug and RM is a real Rx market., The fact that by 2023 Nyxol can be the only FDA-approved drug for this indication should more than justify Ocuphire's ~\$75mm valuation. We continue to believe that RM alone should provide that elusive floor in Ocuphire's valuation and from there added value should be ascribed for presbyopia success (see below), the potential for Nyxol in night vision disturbance (NVD), and APX3330 in diabetic retinopathy and diabetic macular edema (DR/DME).

The market reaction to the RM data was surprising to us, but as we noted, there were reasons we could point to that perhaps explained the stock's behavior. In the time between releasing MIRA-2 results and the release of the Ph2 presbyopia, VEGA-1, results, Ocuphire addressed their balance sheet and structural issues, completing a \$15mm financing and eliminating all anti-dilution provisions from the legacy RTO financing. Granted the \$15mm raise didn't completely alleviate balance sheet concerns and the XBI was still in a funk at the end of June as the company prepared to report VEGA-1 results, but we felt the company had positioned itself for a healthy rebound in the scenario they reported positive presbyopia data. So if we were surprised by the market reaction after MIRA-2, we were shocked by the market reaction after VEGA-1, where Ocuphire announced positive results in what should be a blockbuster indication, only to see the stock briefly spike but fade in the days that followed.

In VEGA-1, the Nyxol + low dose pilocarpine (LDP) treatment arm demonstrated a statistically significant improvement in visual acuity (DCNVA) vs control at 1 hour, meeting the primary endpoint. We could spend a few paragraphs dissecting all the secondary endpoints but the take-home for us was that all efficacy endpoints were numerically superior with Nyxol + LDP, most reaching statistical significance, and for the few near statistical misses, those should be addressable with a larger sample size in Ph3. This was a Ph2 study intended to inform for Ph3, the study met its primary endpoint and most secondaries, it was a clear success in our opinion.

We understood the question marks around RM as an Rx market but were surprised to hear similar questions around presbyopia, especially given that ophthalmology heavyweights Abbvie (Nasdaq: ABBV) and Novartis (NYSE: NVS) are developing drugs for this indication. We would expect that investor cynicism around the presbyopia market to change once Abbvie gets its 1.25% pilocarpine solution approved, likely late-21 / early-22, and hopefully shares its expectations for presbyopia as an Rx market. We would also highlight that although Ocuphire is a few years behind Abbvie in the race to enter the presbyopia market, their Ph2 data for Nyxol + LDP combination compares favorably with Abbvie's Ph3 data for its 1.25% pilocarpine solution, with some potential for efficacy, durability, and tolerability advantages and differentiation.

After a hectic first 6-months of 2021, Ocuphire can now catch its breath before entering another period of steady clinical readouts in 2022. Their Ph3 NVD study, LYNX-1, originally scheduled to report 3Q21 is now scheduled for early-22. Ocuphire has already generated Ph2 PoC data with Nyxol in NVD, and with Nyxol behaving as, or better than, expected in the already reported RM and presbyopia studies, we think LYNX-1 has an above average probability of success. Around the same time as LYNX-1 is reading out, Ocuphire should be reporting data from their second Ph3 study in RM. Later in 2022, we would also expect to see Ph3 presbyopia data for Nyxol. As if reporting three Ph3 studies in one calendar year isn't enough, Ocuphire will also be reporting Ph2 data for its oral small molecule APX3330 for the treatment of DM/DRE sometime during the year.

Processa Pharma (PCSA) Initiated 2/22/21 @ \$10.89, Currently \$6.62

For a little company, Processa has a very busy pipeline, with four unique assets that are either in, or should be in, clinical studies over the next 12-months. As we wrote in our initiation report;

Processa's pipeline is constructed of development-stage assets that have substantial legacy human data, where the company believes a new approach (dosing, indication, trial design, etc.) can unlock latent value. Processa's management (David Young, Questcor) and board (Khalid Islam, Gentium, and Fennec) have a history of successful drug reclamation projects.

Processa expects to spend \$3-\$5mm per asset to generate efficacy data to determine a go / no-go decision. The company is currently enrolling two studies, a Ph1b advanced GI cancer study with PCS6422, and a Ph2b ulcerative necrobiosis lipoidica (uNL) study with PCS499, and expects its other two assets, PCS12852 and PCS3117 to be in the clinic in 2022.

The company's first data release will come from the Ph1b PCS6422 study where Processa should share initial results from the first one or two cohorts later this year. As a reminder, this study will be dose-escalating capecitabine on a background of a fixed dose of PCS6422. We are not sure exactly what data will be disclosed in the interim analysis but we assume Processa will share PK data on PCS6422 and more importantly, capecitabine and its metabolites. If PCS6422 is behaving as expected, we should see improved bioavailability of capecitabine's anti-tumor active metabolites than what is typically seen with monotherapy capecitabine. We should also see less of the side-effect causing inactive metabolite F-BAL.

Processa's other ongoing study is with PCS499 for the orphan indication uNL. This randomized placebo-controlled Ph2b study will enroll 20-patients with uNL. The company disclosed in their mid-August 2Q call that 2 patients were currently enrolled in the study with another in screening. Processa expects to have interim data on 8-10 patients 1H22. Given the current pace of enrollment we would budget for the later part of 1H22 for these interim data. Inter-

estingly since our Processa launch, we have seen other analysts place greater emphasis on PCS499 than on PCS6422 (Matt Gamber, a must-follow on Twitter @mattbiotech, discussed PCS499 at length in his free newsletter here [Matt Biotech's Newsletter PCSA](#), and Opco recently launched on PCSA \$20PT with PCS499 commanding the greatest weight in their model). Although we will see interim data from PCS6422 first, we suspect that PCS499 may end up being the asset that captures investors' attention in 2022.

Processa's other two assets, PCS12852 and PCS3117, will be entering clinical studies in 2022. Processa should begin enrolling a Ph2a gastroparesis study with PCS12852 in 1H22. PCS3117, recently in-licensed from Ocuphire, should enter a Ph2b study, likely in pancreatic cancer patients, in 2H22.

At the risk of sounding like a broken record, Processa, like most of its micro-cap biotech peers, saw its value erode substantially over the last 6-months. Insiders have been stepping up during this time, which is always nice to see. The company had ~\$21mm in cash as of 06/30 which should give them runway through to the end of 2022.

Perimeter Medical (PINK.V, PYNKF) Initiated 10/21/2020 @ CA\$2.01, Currently \$2.55

Since our last update, Perimeter had some notable news on its ImgAssist technology, including positive preliminary data on the performance metrics for ImgAssist, and FDA Breakthrough Device Designation (BDD). Perimeter has never really talked about what performance metrics investors should be looking for or focusing on in the Atlas AI project with ImgAssist, so not surprisingly the area under the curve (AUC) data they shared in April didn't generate much investor fanfare. However poorly these data were communicated, investors shouldn't discount their importance. The 0.94 AUC (sometimes referred to as AUCOC) results generated with ImgAssist on 400 breast tissue images are excellent. The closer the AUC is to 1.0, the better the machine learning model is at distinguishing between patients with or without disease. These early performance results for ImgAssist are highly encouraging, and clearly warrant the company advancing the Perimeter B-Series OCT (formerly referred to as OTIS with ImgAssist AI) into a large RCT. We had expected the RCT to have started by now, so would expect to hear from Perimeter shortly on this study kicking off. Data from the RCT, which we would expect in 2022, will support FDA clearance for Perimeter B-Series OCT, which should be a real "break-through" for breast conservation surgery (BCS) patients and Perimeter investors.

We were pleasantly surprised to learn that Perimeter B-Series OCT had received BDD from FDA. There are unquestionably some regulatory advantages that come with BDD, but the real benefit in our opinion is on the reimbursement front, where BDD devices, once approved by FDA, should immediately qualify for 4-years of national Medicare coverage, through the Medicare Coverage of Innovative Technologies (MCIT) rule. Earning Medicare reimbursement can often be a long and arduous process for medical device companies, so MCIT would be a huge benefit to a small company like Perimeter.

Not surprisingly, Perimeter has been fairly quiet regarding the ongoing commercialization of their FDA-cleared 1st gen Perimeter S-Series OCT. As we stated in our March update,

We will be watching for news on OTIS (now called Perimeter S-Series OCT) 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 continue to recommend investors exercise patience with commercialization news from Perimeter. Our expectation is that Perimeter will provide a meaningful commercial update by YE21, which should hopefully include several installations with leading BCS surgeons and institutions, and foreshadow what kind of revenue ramp investors can expect in 2022. In the meantime, we are encouraged to see Perimeter continue to expand its commercial team with the recent addition of 4 market development managers to support Perimeter S-Series OCT rollout.

Modular Medical (MODD) Initiated 06/07/21 @ \$5.96, Currently \$3.45

Our latest initiation, Modular Medical, recently announced that incumbent board member, Lynn O'Connor Vos was taking over the CEO role from Paul DiPerna. DiPerna, the founder of Modular, will continue to play a large role at Modular as Chairman, President, and CTO, and can now focus exclusively on engineering and R&D. Our initial conversations with CEO Vos have been very encouraging, her marketing and communication expertise from her 20+ years with greyhealth group (ghg) will be needed as Modular prepares to enter the insulin pump market dominated by Medtronic (Nasdaq: MDT), Insulet (Nasdaq: PODD) and Tandem (Nasdaq: TNDM). CEO Vos is also on the board of OptimizeRx (Nasdaq: OPRX) a company she made a strategic investment in while CEO of ghg. The CEO of OptimizeRx, Will Febbo, is also a Modular board member. We aren't overly familiar with the OptimizeRx business, but we can't help but wondering if there isn't a potential business relationship percolating between the two companies.

We continue to expect two key milestones for the company before YE21, both of which should help improve the stock's anemic trading. First, we are expecting the company to list on Nasdaq, likely with a concurrent financing, and second, we expect the company to file its 510(k) for Pivot with FDA.

TLC (TLC) Initiated 04/27/20 @ \$4.25, Currently \$7.20

We are retiring coverage on TLC, after their July announcement of a go-private stock-swap arrangement with Woods Investment Company, Ltd. This effectively is a management buy-out which values TLC at approximately \$7.20 / share and has the support of TLC's largest shareholders. We will continue to monitor TLC as a private company, and hopefully be able to provide an update on the company after it reports its impending Ph3 data for TLC599 in knee OA later this year.

We appreciate your interest and support,

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