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Comparative Biology & Veterinary Biotechnology Sector: Company News Update-Several Lead Products Advance

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The last few weeks have been very busy for our CBVB universe, with all of the leading small-cap vet biotechs reporting clinical development or commercialization progress. As these various products advance towards approval, late 2016 and early 2017 is shaping up to be major watershed period for commercial launches. These events highlight the contrast in industry culture between the "biotech" animal health companies, who are focused on exciting new products being commercialized and the traditional big multi-national animal health organizations who continue to shuffle the chairs in various merger dances playing out across the industry.

The latest news on the merger front is coming from Bayer AG's (BAYZF/$95.00/Not rated) official announcement of its intent to purchase Monsanto (MON/$109.90/Not rated). Bayer's new CEO, Werner Baumann, has noted the difficulty in getting Bayer's animal health business to an appropriate competitive scale as the Company was unsuccessful in a bid for animal health assets from Schering-Plough and it lost to Eli Lilly (LLY/$75.04/Not rated) for the acquisition of Novartis Animal Health. In 2015, with $1.7 billion in companion animal and food production animal vet product sales, Bayer ranked fifth in the group. The pending merger of Sanofi's (SNY/$41.06/Not rated) Merial animal health unit with Boehringer Ingelheim's Vetmedica subsidiary, could soon drop Bayer below the top 5 tier, a primary point in the rationale expressed by market participants that Bayer will put its animal health business on the block if the Monsanto deal goes through. It has been speculated in the press that the unit might garner a price of $7.8 billion or about 4 ½ X revenue.

However, Bayer has not yet backed away from animal health. The Company made recent commitments to expanding its animal health franchise through biotech. On May 10th, the Company formed a vaccine development collaboration with BioNTech AG, to develop production and companion animal vaccines based on BioNTech's messenger RNA technology platform. This collaboration follows a $360 million synthetic mRNA immunotherapy development partnership Sanofi formed with BioNTech in 2015. At the recent Society of Gene and Cell Therapy meeting in Washington earlier this month, Novartis Animal Health and Merial presented posters for novel potential companion biotech products, such as Merial gene-based cellular technology being developed as a one-time treatment for OA in younger dogs.

Key Product News in the Vet Biotech Sector

Kindred Biosciences (KIN/$4.08/Not rated) reported topline results on May 16th of the pivotal field trial for KIND-010, its appetite stimulant drug for cats. KIND-010 is a novel transdermal formulation of mirtazapine, a human tricyclic anti-depressant drug originally approved in 1996 and commercialized as Remeron by Organon Intl., that is also known for its appetite stimulant effects. The difficulty in administration of oral medications

to cats is notorious, but with KIND-010, owners simply administer the novel drug by rubbing it on the inside of their cats' ears. In a placebo-controlled, two-week trial with 231 cats, those who received the drug saw a 4.07% increase in their body weight, versus a 0.29% increase among those on placebo. In the related conference call, management indicated these results were highly statistically significant. Once the data is fully analyzed, KIN expects to release the full results at an "appropriate venue". Inappetence in cats is so common, that according to Company market analysis, small animal veterinarians see an average of 7 cats a week with the condition. If left untreated, it can lead to liver failure. This data will support the upcoming (Q3 '16) filing of Effectiveness Technical Section for KIND-010 with the FDA. Kindred has already filed the CMC section of the New Animal Drug Application and successfully completed the in-life portion of the Target Animal Safety Study. Management noted on the call that from start to expected FDA-approval, the KIND-010 program will have taken a mere 3 years. This accelerated timeline to commercialization with a group of top-tier product acquirers/partners sitting in the wings is one of the reasons we believe vet biotech is gaining increased investor interest.

Earlier this year, Kindred reported positive results from a pivotal trial of Zimeta (dipyrone injection), a drug to treat pyrexia, or fever, in horses. Fever can have important implications for horses, as seen just this week with the owners of Nyquist, the 2016 Kentucky Derby winner, announcing he would not run in the Belmont Stakes due to a fever. Kindred is looking for approval and launch of Zimeta by the end of 2016 or early next year. In preparation, the Company announced the formation of Kindred Bio Equine as a new subsidiary for the equine business. This branded specialty pharmaceutical company will be one of those very few devoted exclusively to equine health and underscores Kindred's commitment to becoming a leader in the field.

Jaguar Animal Health (JAGX/$1.40/Not rated**)** reported progress since our last update on its canine product, Canalevia™. Canalevia is awaiting approval for acute chemotherapy-induced diarrhea (CID) under a MUMS designation (animal orphan drug-like designation) and is expected to be launched in 2017. Canalevia is currently undergoing its pivotal field study (CANA-003) for general acute diarrhea. The 150-dog prospective, blinded, randomized, placebo-controlled study was initiated in December 2015 in animal shelter and rescue centers across the US and should be completed in the second half of 2016. The Company announced that it had obtained a protocol concurrence from the FDA to amend the protocol to use a 125-mg cGMP manufactured crofelemer tablet in the trial so as to align the tablet treatment for both the CID and acute diarrhea in dogs with the same dosage form of the FDA-approved human formulation of crofelemer. Jaguar estimates vets in the US see about six million cases of acute and chronic diarrhea in dogs a year.

Similar to Kindred, Jaguar is also focusing on unmet needs in equine health, for which the Company is developing equine-specific crofelemer formulations to treat diarrhea associated with acute colitis and equine gastric ulcers. Jaguar has completed the pilot safety study for SB-300, its product for equine gastric ulcer syndrome, and recently announced the initiation of a dose-finding study for the SB-300 target commercial paste formulation. The randomized, blinded, placebo-controlled study is enrolling approximately 100 racehorses, two

years or older, who have been diagnosed with an ulcer. Equine patients will be evaluated at 14 and 28 days post-treatment to determine the improvement or resolution of the gastric ulceration. Importantly, SB-300 does not change the pH in the horse's gut and according to tests completed in April 2016 by an independent testing service, horses having received treatment with SB-300 did not have any detectable substances commonly disallowed in performance horse and horse racing competition. The confirmation of the lack of a "withdrawal time prior to competition" is a strong product differentiator compared to current treatments. Studies have shown that over 50% of performance horses have both colonic and gastric ulcers and as many as 97% of performance horses may incur an ulcer of one type or another during their performance period (Source: Pellegrini, FL, J Equine Vet Sci, 2005).

Aratana Therapeutics, Inc. (PETX/$7.13/Not rated) announced on May 17th that it has been granted FDA approval for **ENTYCE®,** the Company's drug for canine inappetence. This is Arantana's second FDA approval this Spring. The approval should allow a commercial launch in late 2016 or shortly thereafter. In other clinical and regulatory news, Aratana anticipates receiving the final remaining major technical section completion letter next month for NOCITA for management of postoperative pain in dogs, which if approved according to the Company's previously disclosed timeframe would enable the product to be launched in late 2016. In addition, Aratana has commenced a safety study for AT-014, a therapeutic vaccine designed for the treatment of canine osteosarcoma, which would support an anticipated USDA conditional licensure in the late 2016.

These regulatory and clinical successes follow on the heels of last month's announcement that Elanco Animal Health, Lilly's animal health company, had entered into an agreement with Aratana for the worldwide exclusive rights to develop, market and commercialize **Galliprant®.** The agreement includes a co-promote deal for the US. Aratana is to receive $45 million as an upfront payment and an additional $83 million upon the achievement of certain milestones. On the Company's first quarter conference call, management noted that moving a portion of commercialization expense to Elanco will now allow Aratana to bring a number of pipeline programs forward including initiating a pivotal field effectiveness study for AT-016 for dogs with osteoarthritis pain, initiating the pivotal field effectiveness study for cats for AT-003, a long-acting post-acute care pain treatment and third, initiating a pivotal field effectiveness study for cats for AT-002 for weight gain, for which Aratana is awaiting a protocol concurrence.

We view the transaction between Elanco and Aratana as particularly significant to the vet biotech space. We believe it sets the stage as products approach commercialization for other such deals. By providing credibility for "vet biotech" as a whole, in much the same fashion as Roche's investment in Foundation Medicine kick-started a significant run in molecular diagnostic companies, we see this transaction becoming a catalyst for expanding awareness of the potential of vet biotech companies. *SG*

Risk Factors

In addition to normal economic and market risk factors that impact most equities, and the common risks shared by the companies named in this sector and those in the biotechnology sector as a whole, we believe an investment in any of the Dawson James Comparative Biology/Vet Biotech Sector companies involves the following risks:

- **Regulatory risks** – The companies in the DJ Comparative Biology/Vet Biotech Sector are subject to regulatory review for their ongoing research and development activities and manufacturing operations with local, state and federal governmental agencies both in the US and Internationally.

- **Need to defend patents, trade secrets and other intellectual property** – Biotechnology companies rely heavily on intellectual property related to their technology and products. While larger companies may have adequate resources to defend their intellectual property, most of the smaller companies in the DJ Comparative Biology/Vet Biotech Sector would be materially and negatively impacted by intellectual property infringement or the loss of one or more patents.

- **Historical lack of profitability** – To date this year and in past years, most of the companies in the DJ Comparative Biology Sector have not operated on a profitable basis, and are not forecast to do so in the immediate future. Although companies typically have been able to raise funds from the capital markets, there can be no guarantee that any particular company will not be able raise additional operating capital in the future should losses continue.

- **Competitive Markets** – This universe of companies operate in a highly competitive marketplace, where speed to market, clinical results and other factors bear on a company's viability. There can be no assurance that any one company will be able to continue to market or later launch its products successfully in these competitive markets in the future.

- **Limited stock liquidity** – Trading volume in some of the companies in the DJ Comparative Biology/Vet Biotech Sector has been comparatively light compared to other stocks in their sector, and as such, news regarding these companies, their target market, partners and/or competitors could lead to significant volatility in their stock price.

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Total	18	100%	13	72%

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