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Sector Analysis Update:
Clinical News Drives Vet Biotech Stock Performance

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Since the middle of April, our Comparative Biology/Vet Biotech index has diverged from its historically close tracking of the Russell 2000. In taking a closer look at various components of the index, it is our observation that a significant portion of the under-performance can be attributable to a divergence that has been occurring between the “human therapy-centric” members and “vet biotech-centric” members of our Comparative Biology/Vet Biotech index.

Echoing this observation was a recent article published on August 24th by **Reuters** entitled, “*Animal Spirits—Consumers’ devotion lifts pet-care stocks*” which was also picked up in an August 29th article in **FiercePharma**, “*Love of pets drives animal health on Wall Street*” (links to both articles are at the end of this update.) Reuters noted that stocks representing the broad arena of pet care were up 35% so far in 2016 compared to a rise of just 8.3% for the S&P 500 in the same time period. The larger cap pet/animal health companies which include players in diagnostics, specialty pet food companies, general pet/animal care, vet clinics and pet insurance, as a group, generally reported year-to-date financial results above expectation and in some cases, have raised guidance for the rest of 2016 and 2017. Trupanion (TRUP/NASDAQ/\$15.08/Not rated), the pet insurance provider, for example, reported its 35th consecutive quarter of revenue growth in excess of 30% on a year-over-year basis. Zoetis (ZTS/NYSE/\$51.25/Not rated) noted in its second quarter report that its US companion animal product sales rose a healthy 17% year-over-year, in part due to the launch of new and innovative products. The Reuters article noted further that the animal health group is enjoying an accelerated rate of consumer spending growth for pets and pet care, up 5% in inflation-adjusted terms in 2015, compared to the general overall rate of consumer spending, which the US Bureau of Economic Analysis pegged at 3.2% in 2015.



When we plot the vet biotech-centric index members against our broader CBVB index, the performance of the veterinary side of the equation becomes readily apparent. In addition, the narrower group performance holds up well against the more general Russell 2000. We believe that in large measure, this out-performance by the vet-centric index members compared to the human-centric index members is due not only to increasing visibility of

the use of companion animals in clinical trials as discussed in a recent article that appeared in **Science**, “*Can Clinical Trials with Dogs and Cats Help People*”, 8/11/2016, but also due to investor recognition of a number of high-value, high-need products on target for launch in 2017. In fact, 2017 is shaping up as a watershed year for the vet biotech sector. We expect further news from the sector to come from this week’s major industry event, the Kansas City Animal Health Corridor Investment Conference and the coinciding veterinary trade event. Over 300 animal health companies are domiciled in the Animal Health Corridor which is located between Manhattan, Kansas and Columbia, Missouri. The next major sector investment event will be **Bio’s** 2nd annual Animal Health Summit to be held in Bethesda, MD in mid-September.

CBVB Index vs. Vet-biotech Index Members

Vet-biotech Index Members vs Russell 2000



Recent News from Vet biotechs

Nexvet Biopharma(NVET/NASDAQ/\$3.91/Not rated): Over the past several weeks, Nexvet has made academic presentations and had peer-review journal articles publish highlighting the clinical progress on its feline osteoarthritis (OA) pain program. Investor response to these events contributed to the stock’s rise from around \$3 in late May to a recent high of \$6.50, before profit-taking took over late last week. Nexvet’s core technology relies on the development of monoclonal antibodies that are 100% species specific (**PETized**) and are based on clinically proven human monoclonal antibody therapies. The Company’s lead products, NV-01, ranevetmab, and NV-02, frunevetmab, are monthly injectable anti-nerve growth factor monoclonal antibody therapies in clinical development for canine and feline OA, respectively.

Following on the announcement in May 2016 of the successful pilot field study of NV-02 in the treatment of pain associated with feline OA, the Company announced it would begin pivotal efficacy and field safety studies later this year for NV-02, which would run concurrently with a pivotal safety study for canine NV-01 that is due to commence in the first half of 2017. At the American College of Veterinary Internal Medicine Forum (ACVIM) held in Denver this past June, Nexvet presented an expanded set of data from both the canine NV-01 pivotal efficacy and field safety trial and the NV-02 pilot feline field trials. In the canine indication, NV-01 showed statistical significance for a number of trial endpoints, including showing a statistically significant improvement on the assessed level of pain as measured using the pain assessment tools Client-Specific Outcome Measures (CSOM), at the day 28 endpoint (p=0.0414), day 56 (p=0.0268) and day 84(p=0.0448). The day 28 endpoint was study’s primary endpoint, as agreed under the FDA Center for Veterinary Medicine’s

(CVM) protocol concurrence. A higher level of statistical significance, $p=0.029$, was shown on Day 28, the only day measured, between NV-01 treated dogs and placebo for the CSOM Global Assessment, which includes overall owner experience with the treatment course.

The feline MV-02 pilot field study incorporated both intravenous and subcutaneous routes of administration and measured endpoints using both CSOM measures and the Feline Musculoskeletal Pain Index measure. The study was a placebo-controlled, randomized, double-blinded field study conducted over 15 US sites that enrolled 126 cats with naturally occurring OA. As measured by the CSOM, NV-02 achieved a statistically significant result ($p=0.0134$) on Day 28 and a stronger result, $p=0.0030$, at Day 56 compared to placebo. Using reduction in the level of pain as measured by a median FMPI score, NV-02 showed a significant improvement over placebo at both Day 42 ($p=0.0002$) and Day 56 ($p=0.0160$). This data supports the Company's proposed once per month treatment schedule.

Peer-reviewed journal articles relating to the characterization of NV-02 and an early NV-02 proof-of-concept study were published in late June in the *Journal of Veterinary Internal Medicine*, a leading veterinary journal for veterinary internal medicine and neurology. Nexvet's Chief Scientific Officer, Dr. David Gearing, also presented the data at the Veterinary Pain Short Course in San Diego on July 29th. These events were well-received by investors as the stock continued to climb through June to its near peak on July 29th.

In other corporate news, Nexvet is making progress in the development of PETized mABs against PD-1 for canine cancer in a research and development collaboration with Zenoaq (Nippon Zenyaku Kogyo Co. Ltd.), a leading Japanese animal health company and the development of anti-tumor-necrosis factor (TNF) compounds directed against a variety of canine and feline inflammatory diseases such as chronic kidney disease, joint inflammatory conditions and atopic dermatitis. Both programs are moving into *in vivo* proof-of-concept. Nexvet announced fiscal yearend 2016 results on September 2nd. The Company reported a FY 2016 net loss of \$19.4 million or \$1.68 per share (11.5 million shares outstanding) compared a FY 2015 net loss of \$11.9 million or \$2.27 per share (5.2 million shares outstanding). Cash on hand at June 30, 2016 was \$31.5 million.

Kindred Biosciences (KIN/NASDAQ/\$4.15/Not rated) has also recently reported progress in its feline clinical program. The Effectiveness Technical Section of the New Animal Drug Application (NADA) for **Mirataz™** (mirtazapine, KIND-010), Kindred's novel transdermal gel for inappetence in cats (management of weight loss) was filed on August 22nd and follows the CMC section filing of May 2016. Kindred expects to file the Safety Technical Section in the third quarter of 2016 which would queue up **Mirataz**, upon approval, for a commercial launch 1H 2017. The efficacy trial's primary endpoint of percentage change in body weight was achieved with a highly significant p-value of $p<0.0001$. 231 cats were enrolled in the multicenter, randomized, double-blinded, placebo-controlled pivotal field study. There are currently no FDA approved treatments for inappetence in cats, of which some 9 million cats in the US may be in need of treatment for undereating, which can lead to hepatic failure/death. About 80% of vets surveyed on intent to use indicated they would prescribe **Mirataz** for feline inappetence, especially since the product is administered transdermally.

Other clinical programs are on track. In June, KIN announced the initiation of a pilot field study in canine atopic dermatitis that will assess the safety and efficacy of KIN's anti-cytokine antibodies, among other molecules, and the pilot field study of **epoCat**, feline erythropoietin for control of non-regenerative anemia in cats, in underway at multiple sites. The pilot field study for KIND-014, Kindred's equine gastric ulcer product, has completed enrollment and the study is expected to be completed in Q3 2016. Start of the KIND-015 pilot field trial in equine metabolic syndrome is expected by yearend. The filing for **Zimeta**, KIN's dipyrone injection treatment for fever (pyrexia) in horses, for which there is no FDA approved treatment, is complete and

based upon feedback from FDA, the Company is expecting approval in 1H 2017. Kindred's market research suggests that as many as 10% of the 8-9 million horses in the US are treated annually for fevers.

In the Company's second quarter conference call, management added that the Company is now positioning for the transition to a commercial operation by adding commercial oriented staff, Head of Commercial Operations and Director of Vet Technical services and an internal sales team. Kindred is also completing its state of art GMP manufacturing facility—one of few in world dedicated to veterinary biologics. The Company reported a net loss of \$4.9 million, or \$0.25 per share, for Q2 2016 compared to a net loss of \$6.9 million or \$0.35 per share in the 2015 period. Cash on hand at June 30th was reported at \$66.3 million.

Jaguar Animal Health, Inc. (JAGX/NASDAQ/\$1.43/Not rated) shares have climbed 10% since Wednesday, August 31st, after announcing yesterday topline data from its **Neonorm™ Calf** study that was conducted in conjunction with the Cornell University College of Veterinary Medicine. The study assessed the efficacy of prophylactic use of a powdered, 2nd generation **Neonorm Calf** formulation in treating naturally occurring diarrhea and dehydration in preweaned dairy calves. **Neonorm** is a standardized botanical extract derived from the Croton lechleri tree. The double-blinded, placebo-controlled, randomized study of 40 newborn Holstein bull calves showed that severe dehydration requiring the administration of intravenous fluid therapy was reduced by approximately 50% in the **Neonorm** treated calves.

This positive data in newborn calves follows similar prophylaxis data generated in a recently completed study of piglets conducted by Chinese investigators of the powdered formulation. As an example, in one of the Chinese multi-site studies which took place between March and May 2016, 433 piglets from two age groups (1-3 days old and 10-15 days old) were treated with **Neonorm** powder in a water formulation. The 1-3 day old group achieved a 99% rate of resolution of diarrhea compared to no resolution in the control group. Mortality was significantly reduced in this age group, with the **Neonorm**-treated piglet group having a mortality rate of just 3% compared to a 100% mortality rate for the untreated group. Resolving diarrhea in piglets, particularly when it may have arisen from Porcine Epidemic Diarrhea Virus (PEDv), a contagious coronavirus, is a significant economic issue to the swine industry. Originating in China, the disease was unknown in the US until May 2013. Between June 2013 and May 2014, approximately 7 million pigs died of the virus in the US. Newly developed vaccines and heightened biosecurity are beginning to control outbreaks although there is still no effective treatment once a piglet has become infected. Jaguar has entered into discussions for an exclusive distribution relationship for pigs and dairy calves with the Chinese business entity involved with the clinical studies.

Aratana (PETX/\$8.92/Not rated) on August 15th, announced that the FDA approved **Nocita®** (bupivacaine), the Company's long-acting injectable drug to relieve pain in dogs after ligament surgery. This is the third FDA approved drug for Aratana this year, and follows **Galliprant®** and **ENTYCE®**. As previously announced, **Galliprant** will be co-marketed with Elanco. **ENTYCE**, indicated for canine inappetence, was approved in May 2016 and will launch commercially in 2017. **Nocita** is expected to become commercially available this fall and will be the first product to be marketed by the Company's newly established internal sales organization, which consists of national and regional sales managers and up to 24 sales reps. The company has not yet disclosed the pricing of its three new products.

Nocita is long-acting local canine anesthetic indicated to immediately alleviate acute pain for up to 72 hours following ligament surgery. Aratana originally licensed the drug from Pacira Pharmaceuticals (PCRX/NASDAQ/\$39.17/Not rated), which makes a bupivacaine injection for use in people. It is because of the direct Pacira relationship that Aratana is able to ramp up production and sales so quickly, the company has said in the past. Aratana is also moving ahead with feline therapeutics. The Company has commenced two clinical

programs (AT-002 and AT-003), both enrolling cats in the pivotal field effectiveness studies for feline post-operative pain with the same active pharmaceutical agent that is in **Nocita**.

In the Company's second quarter 2016 report, management noted the receipt of \$38 million of the \$45 million upfront payment from Elanco. The upfront payment was responsible for PETX reporting net income of \$21.2 million, or \$0.61 per diluted share in Q2 2016 compared to a net loss of \$8 million or \$0.23 per diluted share for the 2015 second quarter. Aratana finished the June 2016 quarter with \$109.5 million in cash.

VetDC, Inc., a private veterinary biotech company focused on cancer therapeutics, is also making substantial clinical progress and may be another company to see a vet biotech product approved and launched in 2017. In a field study for its lymphoma drug, **Tanovea™** (rabacfosadine) that was concluded in June, the Company reported that the 54 dog study, in which **Tanovea** was alternated with doxorubicin every three weeks, delivered an 81% response rate when given to the study's naïve multi-centric canine lymphoma patients. **Tanovea** is a small molecule drug initially discovered by Gilead Sciences (GILD/NASDAQ/\$77.06/Not rated). The study was conducted over eight sites in the US. The overall median progression-free survival (PFS) was 200 days, which was superior the generally reported historical PFS of 81-169 days typically achieved with doxorubicin alone. The current standard of care for dogs with lymphoma is a multi-chemo-drug regimen known as CHOP, is also a harsh treatment regimen that can require up to 16 veterinary visits. The **Tanovea** combination, by contrast, was given in the recent trial in about 6 visits. The data was presented as a late-breaking abstract at the ACVIM in June. **Tanovea** has been administered to over 300 client-owned dogs with naturally occurring lymphoma and is known to have a very rapid onset of action, in some cases in a few as 7 days post-treatment.

On August 24th, Vet-DC received "complete" letters from the FDA's CVM for the three major technical section filings for **Tanovea**. Vet-DC intends to submit the final administrative filing later in 2016, which can only be done following a "complete letter" on prior three technical sections. The Company expects final approval to occur in a timeframe such that **Tanovea** could commence commercialization in early 2017. VetDC was spun out in 2009 from Colorado State University, a leader in the Comparative Oncology Initiative. The Company's mandate is converting novel experimental treatments that have been shelved by pharmaceutical companies to use in veterinary medicine.

Closing Thought: We continue to believe that the realm of comparative biology and its application in the development of novel human and veterinary therapeutics is still not widely recognized on the Street by other analysts or in general by investors. However, the fact that the vet biotech company group have demonstrated execution so far this year by largely advancing clinical programs on schedule is beginning to be noticed. With a significant number of new products from this sector to be commercialized in 2017, our enthusiasm for the entire group remains steadfast and we believe will underlie strong relative market performance. *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 DJ 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/Vet Biotech 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.

Referenced Links:

<http://www.reuters.com/article/us-usa-stocks-pets-idUSKCN10Z2N0>

http://www.fiercepharma.com/animal-health/love-pets-drives-animal-health-wall-street-report?utm_medium=nl&utm_source=internal&mrkid=964451&mkt_tok=eyJpIjoiTURaaFl6YzFNVFkwT1RNMylsInQiOiI2SDdlSXRtdnVWMzIQVHFHMEExLNWwrd0RHbFFDalsQVBhcFVHZGxvUjYyMHFZSm9ldTl4VndOeVJPaGt4bjNiNk93OzNRXC9BZzFkUmpkYlJ6dkZOYkNVWjZ3QlpGTmxrQ3BPOWpUaU5KRDg9In0%3D

<http://www.sciencemag.org/news/2016/08/can-clinical-trials-dogs-and-cats-help-people>

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