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Toll Free: 866-928-0928 ♦ www.DawsonJames.com ♦ 1 N. Federal Highway, 5th floor ♦ Boca Raton, FL 33432

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Comparative Biology & Veterinary Biotechnology Sector: Company News Update

Sherry Grisewood, CFA
Managing Partner,
Life Science Research
917-331-9963
sgrisewood@dawsonjames.com

There have been a lot of "goings on" in the animal health world and, of late, the animal health industry continues to be very fertile ground for M&A. This year's shuffling of animal health businesses among the industry's largest players was kicked off last January when Lilly (LLY/$86.04/Not rated) bought Novartis Animal Health for $5.4 billion. In the most recent M&A news among the top five players, Sanofi (SNY/$42.51/Not rated) confirmed last week it is in exclusive negotiations to exit the industry via a $12.5 billion asset swap with Germany's closely-held pharmaceuticals company, Boehringer Ingelheim. This asset swap follows speculation concerning the fate of Zoetis (ZTS/$47.90/Not rated), the world's largest animal health company, itself the subject of aborted interest from Valeant Pharmaceuticals Intl. (VRX/$110.52/Not rated) last summer. Zoetis is now once again rumored as a possible target for Bayer after Bayer divests its MaterialScience business. Zoetis has fueled its own share of speculation with its possible interest in IDEXX (IDXX/$71.66/Not rated), the animal health diagnostics leader. IDEXX's head of sales is a former Zoetis veteran. And so it goes……

With this past week's announcement, Sanofi would trade its Merial animal health business for BI's consumer health business. Merial is best known as one of the largest marketers of vaccines and treatments for the companion animal market with products such as Heartgard for the prevention of heartworms in dogs, Purevax feline vaccines, and NexGard, a chewable flea & tick remedy. Once completed, the Merial asset swap would make BI's Vetmedica unit the second-largest animal health company in the world behind Zoetis, with estimated 2015 sales of €3.8 billion ($4.2 billion), according to press releases from the companies.

Companies in our Comparative Biology sector have also been generating news. Several, including Aratana (PETX/$6.20/Not rated), Philbro Animal Health (PAHC/$31.84/Not rated) and Nextvet (NVET/$3.73/Not rated), participated in last week's Bank of America Merrill Lynch 2015 Animal Health Summit that was held in Boston. At the Summit, Nextvet discussed the results of its pivotal efficacy study for NV-01, an anti-NGF monoclonal antibody for canine osteoarthritic pain. Nextvet is a developer of species-specific veterinary biologics for companion animals. Its products are based on the Company's proprietary PETization™ platform, which is a rapid design platform for species-specific monoclonal antibodies (mAbs) that are recognized as "self" or "native" by the animal's immune system. Nexvet's product candidates leverage safety and efficacy data from validated human therapeutics and are focused on chronic pain and inflammatory diseases in companion animals.

NV-01 is a 100% canine specific anti-NGF (nerve growth factor) mAb. NGF is a highly conserved cross-species pain signaling modulator that is known to be relevant in the etiology of pain and has already been validated in humans. There are no approved mAb's for canine osteoarthritic pain, and NV-01 is the most advanced monoclonal antibody-based therapy currently in the clinic. The 246 canine patient study, conducted at sites across the US, France and Germany, showed NV-01 was safe and well-tolerated, with no observed significant adverse events in the study's canine patients. Importantly, NV-01 demonstrated a long half-life after a single injection and did not induce neutralizing antibodies in repeat administration. The primary endpoint of the trial was met and as such, provides the basis for the initiation of an efficacy pivotal, multi-center, blinded, placebo-controlled, randomized trial in 2016. Rimadyl, which is credited with creating a prescription NSAID market in companion animals, generated over $270MM in revenue in 2014, only 8 years after its launch. However, significant toxicities are common with the chronic use of NSAIDs in companion animals, much the same as identified in humans and Nextvet believes that monoclonal antibodies can provide a true alternative in chronic pain managment.

The same technology is being deployed to develop a first-in-animal, first-in-kind 100% feline anti-NGF mAb (NV-02) with a superior target profile compared to NSAIDs. There are currently no approved therapies for chronic pain management in cats, as cats have an intolerance to NSAIDs that drives significant renal toxicity even if used for as short a period as three days. The only alternative for feline chronic pain management is the use of opiods. Nextvet is currently conducting a 15 US-site pilot study for NV-02, with a pivotal study scheduled to begin in 2016.

Kindred Biosciences (KIN/$3.95 /Not rated) reported on December 17th the Company had achieved the important milestone of filing its CMC (Chemistry, Manufacturing and Controls) technical section with the FDA as part of the approval process for its KIND-012 small molecule product, indicated for the treatment and control of fever (pyrexia) in horses. The Company expects to complete the Effectiveness Technical Section filing related to the KIND-012 NADA (New Animal Drug Application) by the end of Q1 2016. Kindred previously announced the positive topline results from the KIND-012 pivotal field study. The study was a 138 horse, multicenter, randomized, placebo-controlled study to determine the efficacy of KIND-012. The primary endpoint was 2 degree decline in temperature compared to baseline fever or the resolution of the fever and return to normal temperature, which for horses is 101.0 degrees F. The success rate was approximately 75% vs a 20% success rate for the placebo group and the data generated a highly significant p value of $p<0.0001$. Horses can develop high fevers in response to bacterial or viral infections such as Potomac Fever or equine flu, thus reducing a fever quickly may be necessary for avoid secondary complications from loss of appetite or profuse sweating.

Kindred is a leader and a trail-blazer in the implementation of the comparative biology approach. The Company is developing and optimizing a suite of small molecule biopharmaceuticals and biologics, already validated for safety and efficacy in humans, as target compounds for companion animals (dogs, cats and horses). The Company has a robust pipeline with five small molecules products in development and six biologics. These products are targeting indications for metabolic conditions, inflammation, cancer and pain.

Clinical news was also reported by Jaguar Animal Health (JAGX/$2.10/Not rated). Jaguar is focused on developing first-in-class plant-based therapeutics addressing gastrointestinal conditions, initially in dogs and horses. Yesterday, December 21, Jaguar announced positive results from its pilot dose escalation

safety study being conducted at Louisiana State University for its lead compound, Crofelemer, an active pharmacological agent derived and purified from the Croton lechleri tree, for the treatment of diarrhea associated with acute colitis (colic). The study demonstrated safety at various dosages in horses and confirmed the lack of dose-limiting toxicities that has also been observed in other species. Horses are subject to gastrointestinal colitis (also referred to as colic, "twisted gut" or large bowel inflammation) which can result in death if not quickly and effectively treated. Acute colitis can occur suddenly and is typically in response to a stress event that causes normal Salmonella and C. difficile gut bacteria to become "activated". It results in severe pain, electrolyte imbalances, massive fluid loss and death if the gut becomes too twisted. Bacterial induced colitis has been reported to have fatality rates of between 32% and 60%, while Potomac fever induced colitis has a death rate as high as 35%. Surgery to untwist the bowel or resection the bowel is now a common treatment for a number of cases (mostly high value performance horses) but may cost $10,000 or more. It is not always successful and may not be able to be performed in time. Jaguar is developing species-specific forms of Crofelemer as first-in-class gastrointestinal products for a number of animals in addition to adult horses, including dogs, dairy calves, foals. The compound acts by modulating the flow of ions through the calcium and chloride ion channels and water in the lumen of the intestine.

We are adding Alexion Pharmaceuticals (ALXN/$184.96/Not rated) to our universe due to the Company's novel use of genetic engineered chickens to produce a first-in-man (and first ever treatment) recombinant enzyme replacement product (rhLAL) for lysosomal acid lipase deficiency and cholesteryl ester storage disease (CESD). On December 8th, the FDA approved Alexion's enzyme replacement product, Kanuma (sebelipase alfa), as the first ever treatment for the rare inherited lysosomal acid lipase (LAL) deficiency also known as Wolman disease. Wolman disease becomes evident in early infancy and is a rapidly progressive disease that typically leads to build-up of fats in liver and cardiovascular tissues that eventually results in severe organ damage and death during the first year of life. Wolman's disease afflicts one or two infants per million births, and the less progressive CESD form has an incidence rate of about 25 people per million.

The FDA approval of Kanuma was unique in that it came together with a concurrent approval by the Center for Veterinary Medicine (CVM). The CVM approved Alexion's recombinant DNA (rDNA) construct for chickens as a genetically modifying drug used for the production of rhLAL by treated chickens in the whites of their eggs. Under new rules, since the rDNA construct changes the function or structure of the animal, it is classified as a drug and regulated by the Federal Food, Drug and Cosmetic Act. CDER approved Kanuma, the rhLAL product purified from the egg whites. The chickens treated with the rDNA construct are only used to produce rhLAL and neither chicken nor egg is used in the food chain. Kanuma is administered as a once weekly infusion in rapidly progressing infants six months or less in age and as a bi-weekly infusion for infants over 6 months of age and for adults. Alexion received Orphan Drug status, FDA breakthrough designation and priority review, as well as was granted a very rare pediatric disease priority review voucher for the development of Kanuma.

Lastly, a correction on Vet-DC: In our Sector inaugural report of December 8th, we highlighted Vet-DC as an example of the cross-over between human and animal health therapeutic development. We were a bit overly optimistic concerning the regulatory status of Tanovea, the Company's lead product for canine lymphoma. Contrary to our optimism, we stand corrected in that Tarnovea has not yet received FDA conditional approval. We will enthusiastically be awaiting Tanovea's FDA approval news. *SG*

DAWSON JAMES COMPARATIVE BIOLOGY & VET BIOTECHNOLOGY SECTOR

Ticker	Security Name	Last	Chg	%Chg	CVol	YTD %Chg	Mkt Cap MM's	EPS FY1	PE FY1	Div Yld
ABSCF	AB Science SA	14.56	0	0.00%	0	2.75%	460	-0.57	--	0
NVET	Nexvet Biopharma PLC	3.8	0.07	1.88%	16,781	--	43	-1.89	--	0
ALQA	Alliqua BioMedical, Inc.	2.09	0.04	1.95%	28,054	-60.57%	57	-0.96	--	0
BIOG.B-OME	BioGaia AB Class B	289	11	3.96%	8,934	61.00%	4,820	7.15	40.39	1.73
PAHC	Phibro Animal Health Corpor	31.87	0.03	0.09%	20,923	1.01%	1,249	1.71	18.64	1.26
PARN	Parnell Pharmaceuticals Holdi	4.14	0.01	0.24%	102	-0.24%	55	-1.05	--	0
KIN	Kindred Biosciences, Inc.	3.96	0.01	0.25%	62,692	-46.85%	78	-1.49	--	0
ICCC	ImmuCell Corporation	7.4	0.06	0.82%	528	52.26%	22	--	--	0
NEOG	Neogen Corporation	57	-3.25	-5.39%	197,795	14.93%	2,251	1.04	54.89	0
OASM-OME	Oasmia Pharmaceutical AB	10.55	-0.05	-0.47%	111,332	-47.25%	1,119	--	--	0
ONCS	OncoSec Medical Incorporat	2.85	0.37	15.04%	176,770	-69.65%	42	-1.63	--	0
JAGX	Jaguar Animal Health, Inc.	2.22	0.12	5.71%	1,506	--	17	-3.27	--	0
VETO-PAR	Vetoquinol SA	39.3	0	0.00%	536	9.47%	467	2.24	17.57	0.99
ENTB	Entest BioMedical, Inc.	0.02	0.01	82.93%	100	0.00%	0	--	--	0
RGS-ASX	Regeneus Ltd.	0.1	0	4.17%	30,000	-37.50%	21	-0.02	--	0
ANAC	Anacor Pharmaceuticals, Inc.	102.31	-2.98	-2.83%	110,825	217.24%	4,646	-1.28	--	0
SRNE	Sorrento Therapeutics, Inc.	8.95	1.14	14.60%	1,280,962	-11.12%	295	-1.56	--	0
NVC-TSE	Neovasc Inc.	4.99	0	0.00%	3,200	-35.19%	332	-0.5	--	0
CTIX	Cellceutix Corporation	1.33	-0.05	-3.62%	235,055	-69.70%	164	--	--	0
DPH-LON	Dechra Pharmaceuticals PLC	10.8	0.28	2.66%	57,023	29.11%	926	0.43	25.09	1.57
GNVC	GenVec, Inc.	1.9	-0.05	-2.56%	21,787	-8.65%	34	-0.37	--	0
SCYX	SCYNEXIS, Inc.	6.16	0.39	6.76%	7,105	-38.28%	80	-2.58	--	0
DPH-LON	Dechra Pharmaceuticals PLC	10.8	0.28	2.66%	57,023	29.11%	926	0.43	25.09	1.57
ANIK	Anika Therapeutics, Inc.	38.4	0.61	1.62%	32,894	-5.73%	553	1.82	21.07	0
TRUP	Trupanion, Inc.	8.97	0.04	0.45%	28,172	29.44%	253	-0.57	--	0
CYDY	CytoDyn Inc.	0.81	0	0.00%	16,234	-29.57%	75	--	--	0
ORNBV-HEL	Orion Oyj Class B	30.7	-0.25	-0.81%	74,777	19.13%	4,366	1.48	20.78	4.23
SAC-ETR	SANOCHEMIA Pharmazeut	1.46	0	0.00%	2,100	49.74%	19	-0.05	--	0
KPTI	Karyopharm Therapeutics, In	14.44	0.88	6.49%	97,262	-61.42%	485	-3.21	--	0
SNTA	Synta Pharmaceuticals Corp.	0.32	0	-0.43%	420,874	-87.75%	45	-0.61	--	0
SRNE	Sorrento Therapeutics, Inc.	8.95	1.14	14.60%	1,280,962	-11.12%	295	-1.56	--	0
ALXN	Alexion Pharmaceuticals, Inc.	184.88	-0.19	-0.10%	259,487	-0.08%	41,701	4.97	37.18	0
PETX	Aratana Therapeutics, Inc.	6.21	-0.03	-0.48%	232,616	-65.15%	218	-1.79	--	0

Private	Blaze Biosciences	Novel imaging agent used to define tumor margins during surgery; canine studies supported NIH grant
Private	Susavion	Novel peptided immunotherapies based C-type and I-type lectins. Just initiated canine trial for lead compound
Private	Juvaris BioTherapeutics	Novel cancer vaccines based on cationic lipid/DNA complexes. Canine allogenic tumor vaccine trial started
Private	MetaMorphix Inc.	Canine genetic testing
Private	Protein Sciences	Novel vaccines, FluBlok (trivalent flu vaccine) is genetically produced vaccine using canine kidney cells
Private	GeneQuine	Novel gene therapy directed against Il-1r for equine and human osteoarthritis
Private	Vet-DC	Novel acylic nucleotide analogue, Tanovea, awaiting conditional approval in canine lymphoma
Private	Vet-Stem Biopharma	Allogenic adipose-derived stem cells for a number of indications

Prices as of December 22, 2015

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 Sector companies involves the following risks:

- **Regulatory risks** – the companies in the DJ Comparative Biology 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 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.

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2) **Neutra**l: the analyst believes the price of the stock is fairly valued for the next 12-18 months;
3) **Sel**l: the analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

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	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	16	67%	10	63%
Market Perform (Neutral)	8	33%	6	75%
Market Underperform (Sell)	0	0%	0	0%
Total	24	100%	16	67%

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