

# **Aratana Therapeutics, Inc.** (PETX)

Initiating Coverage at Market Outperform; Survey Validates Opportunities

MARKET DATA	
Price	\$10.12
52-Week Range:	\$6.56 - \$10.32
Shares Out. (M):	19.9
Market Cap (\$M):	\$201.0
Average Daily Vol. (000):	21.0
Source: Thomson Reuters and JMP Securities LLC	

FY DEC		2013E	2014E	2015E
Revenue (\$M)	1Q	\$0.0A	\$0.0	
	2Q	\$0.0	\$0.0	
	3Q	\$0.0	\$0.0	
	4Q	\$0.0	\$0.0	
	FY	\$0.0	\$0.0	\$0.0
EPS	1Q		(\$0.30)	
	2Q		(\$0.28)	
	3Q	(\$0.14)	(\$0.27)	
	4Q	(\$0.16)	\$0.12	
	FY	(\$0.57)	(\$0.72)	(\$0.65)
	P/E	NM	NM	NM
Source: Company re	eports a	nd JMP Securitie	s LLC	



MARKET OUTPERFORM | Price: \$10.12 | Target Price: \$16.00

# **INVESTMENT HIGHLIGHTS**

We are initiating coverage of Aratana Therapeutics with a Market Outperform and establishing a \$16 price target. Aratana has an active in-licensing effort focused on identifying human therapeutics for development and commercialization as pet therapeutics. We believe the company offers a compelling investment opportunity because it: 1) is poised to benefit from attractive growth of the pet industry, 2) the company's strategy carries less regulatory and commercial risk than human therapeutic development, 3) has a management team with substantial experience in the field of pet therapeutic development, and 4) has a pipeline of unique products that target unmet needs in the pet market. Aratana has three compounds in development: AT-001 for osteoarthritis, AT-002 for inappetance, and AT-003 for post-operative pain. Our independent survey of 50 veterinarians found that the combined U.S. market opportunity for AT-001 and 002 alone is at least \$273 million, with 96% of respondents indicating that they would begin using the product within 12 months. Given the infancy of the animal health industry, we utilized several methodologies in valuing PETX including discounted cash flow (DCF), EV to revenue, and peer comparables. Our target price of \$16 is based on the average of our discounted cash flow analysis (DCF) valuation of \$16 and the relative valuation of \$17, using an enterprise value to revenue valuation methodology.

Aratana Therapeutics is a pure-play biopharmaceutical company developing multiple products focused on the companion animal market. Aratana has an active in-licensing effort focused on identifying human therapeutics for development and commercialization as pet therapeutics.

Poised to benefit from the attractive growth profile of the pet industry. In addition, we view the pet therapeutics industry as less exposed to the headwinds facing the human therapeutics industry. Lastly, management team's deep industry experience should position the company well to execute its plan to develop and commercialize therapeutics for pets.

**Aratana has built an attractive pipeline of products**. Currently, the company is developing AT-001 for the treatment of pain and inflammation associated with osteoarthritis in dogs, AT-002 for the treatment of inappetance in both cats and dogs, and AT-003 for the treatment of post-operative pain.

We surveyed 50 veterinarians with practice revenues north of \$1 million to gauge their interest in several of Aratana's key products. Our survey independently values the total U.S market opportunity for AT-001 and AT-002 alone at \$273 million. Our survey results suggest that 96% of all veterinarians would begin prescribing the therapeutics within 12 months of launch.

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Aratana focuses on developing and commercializing therapeutics for the companion animal market

Aratana has licensed three compounds, AT-001, AT-002, and AT-003 that the company is developing into six products for use in pets in the U.S. and Europe.

Proprietary survey validates market opportunity for pipeline candidates

The veterinary care segment has been among the fastest growing segments of the overall \$53 billion U.S. pet market

Developing pet therapeutic is more capital efficient than developing human therapeutics

# **INVESTMENT THESIS**

# Aratana Therapeutics is a pure-play biopharmaceutical company developing multiple products focused on the companion animal market.

Founded in 2010, Aratana is a development-stage biopharmaceutical company focused on the licensing, development, and commercialization of prescription medications for companion animals (i.e., pet therapeutics). Aratana has an active in-licensing effort focused on identifying human therapeutics for development and commercialization as pet therapeutics. With a focus on both cats and dogs, a single, in-licensed drug candidate can offer two therapeutic programs, each of which can potentially offer its own arrangement with specific development milestones and royalties.

# Aratana has an attractive pipeline of pet therapeutics in development

Aratana has built an attractive pipeline of products. The company has in-licensed three compounds, AT-001, AT-002, and AT-003 that are being developed into six products for use in cats and dogs in the United States and Europe. Currently, Aratana is conducting dose confirmation studies for AT-001 for the treatment of pain and inflammation associated with osteoarthritis in dogs and for AT-002 for the treatment of inappetance in both cats and dogs. Aratana expects to initiate dose confirmation studies for AT-003 for the treatment of post-operative pain in both cats and dogs in mid-2013.

## Proprietary veterinary survey validates key market opportunities

We surveyed 50 veterinarians with practice revenues north of \$1M to gauge their interest in several of Aratana's key products. Our survey independently sheds light on current prescription patterns for osteoarthritis and inappetance. A conjoint analysis of the relationship between pricing and prescription patterns suggests that the U.S. market opportunity for AT-001, when priced at \$1.25/day (25% premium to the market), is \$167M, while the U.S. market opportunity for AT-002 is approximately \$107M (when priced at \$2.00 per day). Our survey results suggest that 96% of all veterinarians would begin prescribing the therapeutics within 12 months of launch.

# Aratana Therapeutics is poised to benefit from the attractive growth profile of the pet industry.

The companion pet market has grown from \$28 billion in 2001 to \$53 billion in 2012, representing a CAGR of ~6%, with an annual industry growth rate of ~3-5% over the next three years. The veterinary care segment has been among the fastest growing segments of the overall companion pet market, and we view the pet therapeutics market as an attractive investment opportunity within which Aratana Therapeutics is well positioned, in our view. Favorable megatrends such as the growth of a global middle class with increased discretionary spending on pets and higher pet ownership in both developed and emerging countries are expected to drive the continued growth of the pet therapeutics market in coming years.

# We view the pet therapeutics industry as less exposed to the headwinds facing human therapeutics.

We believe the following key differentiating characteristics of pet therapeutics compare favorably with human therapeutics, including: (i) faster, less expensive, and more predictable development, (ii) economic alignment between veterinarians and therapeutics companies, (iii) limited government and third-party payer exposure, and (iii) limited impact of generic drugs. We believe these factors position the pet therapeutics industry for a sustainable growth profile.



Deep expertise in the animal health and biotech product development

# Management team's deep industry experience should position the company well to execute its plan to develop and commercialize therapeutics for pets.

The members of Aratana's management team have extensive experience in the development, regulatory approval, and commercialization of pet therapeutics. Aratana Therapeutics' management team consists of veterinarians, physicians, scientists, and other professionals that apply the core principles of drug development to the medical needs of pets. The team has deep networks in the animal health and biotech space, solid clinical and regulatory expertise, and strategic relationships with clinical research organizations (CROs), and we believe this provides Aratana with a substantial competitive advantage.

### **VALUATION**

Given the infancy of the animal health industry, we utilized several methodologies in valuing PETX, including discounted cash flow (DCF), EV to revenue, and peer comparables. Our target price of \$16 is based on the average of our discounted cash flow analysis (DCF) valuation of \$16 and relative valuation of \$17, using an enterprise value to revenue valuation methodology.

## **Enterprise Value to Revenue Methodology**

We find EV/revenue as an appropriate basis given Aratana's incremental revenue growth profile expectation and product development in coming years. We supplement the EV/sales methodology with peer valuation comparisons as our basis for deriving Aratana's price target, as progress on development milestones relative to peer performance can drive the valuation of the company in the near term. From a comparable standpoint, there are not many large publicly traded animal health companies; Zoetis (ZTS) and French-based Virbrac (VIRP) are the only other public names in the space, and there is no single direct comp group for Aratana Therapeutics, Inc. However, we looked across the healthcare sector for companies with similarities to Aratana's profile. This included cash-pay businesses with minimal patent exposure and similar longer-term macro drivers in the growing middle class. With that, we view Allergan (AGN, MO, \$115 PT), Perrigo (PRGO, NC), Monsanto (MON, NC), and Mead Johnson (MJN; a 2009 spin-off of Bristol Meyers, NC) as the best comps against which to value Aratana. Overall, the group is trading at 3.7x EV/2014 revenue. Our relative valuation target assumes PETX can trade at 3.3x EV/2014 revenue, or a 10% discount to its peer average (3.7x).

**FIGURE 1. Comparable Companies** 

	Ticker	Price	Mkt Cap	Ent. Value	NTM Est. Sales	EV / NTM Est. Sales	NTM Est. EPS	Current FY EPS Est.			PE Curr. FY		Current FY EBITDA		Current EV/EBITDA	Next FY EV/EBITDA
Healtho	are S	Select	ted Co	omps											•	•
Allergan	AGN	\$104.18	\$31,629	\$33,807	\$6,254.4	5.4x	\$4.92	\$4.75	\$5.45	21.2x	21.9x	19.1x	\$2,221	\$2,497	15.2x	13.5x
Perrigo	PRGO	\$119.64	\$11,308	\$12,329	\$3,943.4	3.1x	\$6.39	\$5.62	\$6.61	18.7x	21.3x	18.1x	\$907	\$1,025	13.6x	12.0x
Monsanto	MON	\$108.12	\$58,482	\$60,672	\$15,673.0	3.9x	\$4.89	\$4.63	\$5.29	22.1x	23.4x	20.4x	\$4,345	\$4,857	14.0x	12.5x
Mead Johnson	MJN	\$78.97	\$16,047	\$17,552	\$4,234.7	4.1x	\$3.37	\$3.28	\$3.69	23.4x	24.1x	21.4x	\$1,047	\$1,157	16.8x	15.2x
Virbac Fr	VIRP	\$160.70	\$1,359	\$1,395	\$799.9	1.7x	\$8.70	\$8.29	\$9.29	18.5x	19.4x	17.3x	\$141	\$154	9.9x	9.1x
Sector		\$571.61	\$118,825	\$125,755	\$30,905	3.7x	\$28.27	\$26.56	\$30.32	20.2x	21.5x	18.9x	\$8,662	\$9,689	14.5x	13.0x

Source: Thomson Reuters, JMP Securities LLC



## **Discounted Cash Flow Methodology**

We establish our price target of \$16 using a DCF valuation methodology. We value Aratana based on our revenue and expense forecasts for various compounds currently under development (AT-001, AT-002, and AT-003) using a DCF analysis through 2025, assuming product launch in the U.S. in 2016. We believe a DCF analysis represents an appropriate valuation methodology, as it takes into account the pet therapeutics industry growth expectations driven by increased pet ownership among the growing middle class and growth in discretionary spending from emerging economies. We apply a terminal growth rate of 2.5% to reflect the industry growth expectations, and a 15% discount rate to account for technology and execution risk. Based on that, our DCF model suggests Aratana should deliver \$369 million in enterprise value (sum of cumulative cash flows). After we adjust for cash and debt, we arrive at a fair value of approximately \$16 per share.

## FIGURE 2. Discounted Cash Flow Model

Aratana Therapeutics, Inc														
Commercial P&L														
(\$'s in 000's)														
(\$5 111 000 5)							Auston - Ti	herapeutics Pro	in adiana					
		2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Revenue		20.0	2011	2010	20.0	2011	2010	2010	2020	2021	2022	2020	2021	2020
Total Wholesale Revenue		\$0	\$0	\$0	\$26,983	\$89,687	\$139,702	\$193,107	\$255,573	\$310,723	\$347,802	\$381,980	\$413,415	\$439,396
Distributor Margin & ISO		0	0	0	5.962	19.842	30.975	42.866	56,786	69.048	77.259	84,832	91.788	97.520
Gross Revenue	_	0	0	0	21,021	69.845	108,727	150,241	198,786	241,675	270,543	297,149	321.627	341.876
Total Discounts and Rebates		0	Ö	0	2,225	4,350	5.713	6,126	6,211	6,269	6.328	6,386	6,444	6,502
Net Revenue	_	0	0	0	18,796	65,495	103,014	144,115	192,575	235,406	264,216	290,763	315,183	335,374
Total Royalties & Adjustments		1.000	5.500	3.500	2.095	7.056	10,578	14.394	18.807	22,918	25,927	28.667	31,253	33,519
Revenue after Royalties	-	(1,000)	(5,500)	(3,500)	16,701	58,439	92,435	129,720	173,768	212,488	238,289	262,096	283,930	301,855
% Revenue Growth		n/a	n/a	n/a	n/a	250%	58%	40%	34%	22%	12%	10%	8%	6%
Total COGs		0	0	0	3.347	11.133	17.363	24.017	31.802	38.667	43,272	47.519	51.422	54,642
Gross Profit (US)	_	(1,000)	(5,500)	(3,500)	13,354	47,305	75,072	105,704	141,965	173,820	195,016	214,577	232,508	247,213
Milestones & Royalties (OUS)		908	7,900	10,684	9,254	5,830	9,081	12,552	16,612	20,197	22,607	24,829	26,872	28,561
Gross Margin	_	(92)	2,400	7,184	22,608	53,135	84,153	118,256	158,578	194,017	217,623	239,406	259,380	275,774
% Gross Margin		n/a	n/a	n/a	135%	91%	91%	91%	91%	91%	91%	91%	91%	91%
Total S&M		1,254	1,317	5,347	21,495	28,996	36,757	42,952	41,452	42,186	42,936	43,701	44,483	43,521
% of Revenue		n/a	n/a	n/a	129%	50%	40%	33%	24%	20%	18%	17%	16%	14%
Total R&D		7,579	12,980	12,716	7,470	8,637	9,575	10,603	11,814	12,885	13,605	14,269	14,880	15,384
% of Revenue		n/a	n/a	n/a	45%	15%	10%	8%	7%	6%	6%	5%	5%	5%
Total G&A		2,446	2,568	2,696	2,750	3,438	4,636	6,485	8,666	10,593	11,890	13,084	14,183	15,092
% of Revenue		n/a	n/a	n/a	16%	6%	5%	5%	5%	5%	5%	5%	5%	5%
Total Operating Expenses	_	11,279	16,865	20,759	31,715	41,071	50,968	60,040	61,932	65,665	68,431	71,055	73,546	73,998
Operating Income		(\$11,371)	(\$14,465)	(\$13,575)	(\$9,107)	\$12,064	\$33,185	\$58,216	\$96,645	\$128,353	\$149,192	\$168,351	\$185,834	\$201,776
							I	OCF Valuation						
Operating Income	_	(11,371)	(14,465)	(13,575)	(9,107)	12,064	33,185	58,216	96,645	128,353	149,192	168,351	185,834	201,776
Less: Income Taxes	35%		-	-	-		-	12,232	33,826	44,924	52,217	58,923	65,042	70,622
After-Tax Operating Income		(11,371)	(14,465)	(13,575)	(9,107)	12,064	33,185	45,984	62,820	83,429	96,975	109,428	120,792	131,154
Less: Net Change in W/C			-	,	(1,880)	(4,670)	(3,752)	(4,110)	(4,846)	(4,283)	(2,881)	(2,655)	(2,442)	(2,019
Unlevered Free Cash Flow (FCF)	_	(11,371)	(14,465)	(13,575)	(10,987)	7,394	29,433	41,874	57,974	79,146	94,094	106,774	118,350	129,135
PV of FCF		(10,603)	(11,729)	(9,572)	(6.736)	3.942	13.646	16.881	20.323	24,127	24.942	24.611	23.722	22,507
1 7 011 01		(10,003)	(11,723)	(3,312)	(0,730)	3,342	13,040	10,001	20,323	24,121	24,542	24,011	23,122	22,307

Discount Rate	15.0%
Perpetuity Growth Rate	2.5%
Present Value of Cash Flows (\$ 000s)	\$136,062
Present Value of Terminal Value (\$000s)	\$180,058
Enterprise Value (\$000s)	\$316,119
Net Cash at IPO (\$000s)	\$15,000
Debt (\$000s)	\$5,000
Equity Value (\$000s)	\$326,119
Projected Share Count (000s)	19,860
Equity Value Per Share (\$/share)	\$16

	Equity Value Per Share										
	Perpetuity Growth Rate										
		0.0%	2.5%	5.0%							
	13.0%	\$20	\$23	\$27							
Discount	14.0%	\$17	\$19	\$22							
Rate	15.0%	\$15	\$17	\$19							
	16.0%	\$13	\$14	\$16							
	17.0%	\$12	\$13	\$14							

Source: JMP Securities LLC, Company filings



## **INVESTMENT RISKS**

# Limited operating history and significant losses

The company is a development-stage company with a limited operating history and significant losses since its inception. Aratana is expected to continue to incur losses in the short- to medium-term, as it continues the development of product candidates. The previous losses, combined with expected future losses, will continue to have an adverse effect on stockholders' equity and working capital.

## Dependence on the success of the three compounds currently in development

Aratana currently has no products approved for commercial distribution. To date, the company has invested much of its efforts and financial resources in the in-licensing, research, and development of AT-001, AT-002 and AT-003, which are currently the only product candidates and are still in development. If Aratana is not successful in commercializing one or more product candidates, operating results will be negatively impacted.

# Regulatory environment

The denial or delay of regulatory approval (i.e., FDA, EMA) for Aratana's existing and future product candidates would delay commercialization efforts and adversely impact the potential to generate revenue and operating results.

## Market acceptance/commercial success

Even if the current or future product candidates obtain regulatory approval, they may fail to achieve market acceptance and commercial success, which would adversely affect the company's operating and financial results.

# Financing risk

On June 27, 2013, Aratana completed an initial public offering, issuing 5.8 million shares of common stock at a price of \$6.00/share, resulting in net proceeds of \$35 million. The company plans to use the net proceeds of the offering to: (i) in-license and develop additional product candidates, (ii) commercialize its current and future product candidates, (iii) establish a direct sales organization in the U.S., and (iv) for general corporate and working capital purposes. The cash on hand should be enough to fund clinical efforts for AT-001,AT-002, and AT-003 to completion. However, the company will need to raise additional capital in order to successfully commercialize these products and expand its product pipeline.



Aratana develops biopharmaceuticals for use in companion animals

Aratana has licensed three compounds, AT-001, AT-002 and AT-003 that the company is developing into six products for use in pets in the U.S. and Europe.

### **COMPANY OVERVIEW**

## **Company Description**

Founded in 2010, Aratana is a development-stage biopharmaceutical company focused on the licensing, development, and commercialization of prescription medications for companion animals (i.e., pet therapeutics). The companion animal market represents a sizable opportunity with a number of therapeutic and medical needs that have yet to be fully realized or met. Aratana has an active inlicensing effort focused on identifying human therapeutics for development and commercialization as pet therapeutics. This model enables human health-focused pharma and biotech companies to extend drug candidates to the companion animal market. With a focus on both cats and dogs, a single, inlicensed drug candidate can offer two therapeutic programs, each of which can potentially offer its own arrangement with specific development milestones and royalties. Additionally, Aratana is developing its own commercial operations to potentially bring its current and future in-licensed drugs to market.

Aratana has licensed three compounds, AT-001, AT-002, and AT-003 that the company is developing into six products for use in pets in the United States and Europe. Currently, Aratana is conducting dose confirmation studies for AT-001 for the treatment of pain and inflammation associated with osteoarthritis in dogs and for AT-002 for the treatment of inappetance in both cats and dogs. The company plans to initiate dose confirmation studies for AT-003 for the treatment of post-operative pain in both cats and dogs in the second half of 2013. As a development stage company, Aratana has not generated any revenue. The company has incurred net losses of \$3.5 million and \$11.6 million for the years ended December 31, 2011 and 2012, respectively. As of December 31, 2012, Aratana had accumulated a deficit of \$22.2 million and cash, cash equivalents, and short-term investments of \$20.4 million.

FIGURE 3. Upcoming Milestones

Timing	AT-001	AT-002	AT-003	Projected Milestones
1Q13	•			Start dog pilot/pivotal field trial
3Q13	•			Confirmation of effective dose in dogs
2H13		•		Start dog pilot/pivotal field trial
Late 2013			•	Initiation of dose confirmation studies in both cats and dogs
1Q14	•			FDA/CVM review of 9-month tox study complete
2Q14	•			Completion of pivotal field trial in dogs
3Q14	•			Completion of pivotal field trial in cats
1H16		•		Expected approval in US- Dogs
2H16		•		Expected approval in US- Cats
2016	•			Expected approval in US
2016			•	Expected approval in US
1H17		•		Expected approval in EU- Dogs
2H17		•		Expected approval in EU- Cats
2017	•			Expected approval in EU
2017			•	Expected approval in EU



# **PIPELINE PRODUCTS**

Aratana currently has licensed three compounds, AT-001, AT-002, and AT-003 that the company is developing into six products for use in pets in the United States and Europe (Figure 4). Figure 5 highlights the company's typical development timeline for its licensed compounds.

# FIGURE 4. Aratana's Product Pipeline - Licensed Compounds in Development

Compound (Licensor)	<b>Species</b>	Indication	Development Status	Expected Next Step
AT-001 (RaQualia)	Dog	Pain and inflammation associated with osteoarthritis	Dose confirmation study ongoing	Pivotal field effectiveness study
A1-001 (Raqualla)	Cat	Pain management	Selection of indication	Dose confirmation study
AT-002 (RaQualia)	Dog	Stimulation of appetite	Dose confirmation study ongoing	Pivotal field effectiveness study
A1-002 (Raqualla)	Cat	Stimulation of appetite	Dose confirmation study ongoing	Pivotal field effectiveness study
AT-003 (Pacira)	Dog	Post-operative pain management	Proof of concept study ongoing	Dose confirmation study
AT-005 (Facila)	Cat	Post-operative pain management	Proof of concept study ongoing	Dose confirmation study

Source: Company reports, JMP Securities LLC

# FIGURE 5. Aratana's Development Schedule/Timeline

Project AT-XXX		Ye	ar 1			Year 2			Year 3			Year 4				Year 5				Year 6				
FTOJECT AT-XXX	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Proof of Concept																								
Target Animal Safety													©											
Effectiveness													©											
Chemistry, Manufacturing and Controls (CMC)																©								
FDA/CVM Meetings			•			•		•			•													
Approval																,								

© = Technical Section Complete Letter



Expected Approval US
Expected Approval EU

Source: Company reports, JMP Securities LLC



AT-001 is being developed to treat pain and inflammation associated with osteoarthritis in cats and dogs.

#### AT-001 FOR OSTEOARTHRITIS

AT-001 is a selective prostaglandin E receptor 4(EP4), antagonist that Aratana in-licensed from RaQualia (Pfizer spin-out). AT-001 was originally discovered by Pfizer and achieved proof of concept in treatment of osteoarthritis pain in two Phase II human clinical trials . RaQualia has announced the results of a Phase IIa clinical trial confirming that the AT-001 compound, also known as RQ-7, has an equivalent effect on pain as non-steroidal anti-inflammatory drugs, or NSAIDs, and has shown through endoscopic exams, that it is safer for the gastrointestinal tract than NSAIDs. Aratana is developing AT-001 to treat pain and inflammation associated with osteoarthritis in dogs and it is evaluating AT-001 for pain management in cats.

Osteoarthritis is the most common inflammatory joint disease in pets. The prevalence of osteoarthritis increases with age, usually occurring in cats and dogs aged nine years or older, but it can occur even in young animals. According to industry sources, the number of pets diagnosed with arthritis has significantly increased over the past five years and an estimated 13% of all geriatric dogs, and 22% of geriatric large and giant breed dogs, are diagnosed with arthritis. Many dogs with arthritis remain undiagnosed. Osteoarthritis is a progressive disease that can first manifest itself with periodic signs of stiffness or lameness and can progress to where the pet is experiencing constant joint pain and stiffness. Affected cats and dogs may show signs of irritability and reclusiveness.

Osteoarthritis is diagnosed in animals by the veterinarian using clinical signs and radiographs. The disease is incurable, but treatment can improve the cat's or dog's quality of life. Treatment includes a combination of rest, avoidance of overexertion, reduction in weight, proper exercise, and a regimen of pain and anti-inflammatory drugs. In some cases, surgery to relieve the pain or correct deformities or instability may also be employed.

NSAIDs are commonly used to treat pain and inflammation in companion animals.

## **Currently Available Treatments and Limitations**

Analgesic and anti-inflammatory drugs are often used to control pain in cats and dogs with osteoarthritis. The currently approved products for control of the pain and inflammation associated with osteoarthritis in dogs are NSAIDs from the class of cyclooxygenase (COX), inhibitors, or Coxibs. The arachidonic acid pathway constitutes the main mechanism for the production of pain and inflammation in osteoarthritis. This pathway also controls other important body functions such as kidney regulation, gastrointestinal mucosal protection, thrombosis, and blood flow through the enzymatic synthesis of mediators in multiple steps along the pathway. Three COX isoenzymes have been identified—COX-1, COX-2, and COX-3. COX-2 initiates the biosynthesis of prostaglandin-I<sub>2</sub>, or PGI<sub>2</sub>, and prostaglandin-E<sub>2</sub>, or PGE<sub>2</sub>. PGI<sub>2</sub> affects gastrointestinal mucosa, kidney function, and blood flow. PGE<sub>2</sub> also affects gastrointestinal mucosa and is a key mediator of pain and inflammation. The inhibition of COX enzymes to provide relief from pain and inflammation is the mode of action of NSAIDs.

The first product approved for the control of pain and inflammation associated with dog osteoarthritis was Rimadyl (carprofen). The first product approved for the control of pain and inflammation associated with canine osteoarthritis was Rimadyl (carprofen). The introduction of this product created a product category around a previously unmet medical need and fundamentally changed the management of chronic pain in dogs. Rimadyl is a moderately selective inhibitor of COX-1 and COX-2 in dogs. While side effects in most dogs are generally mild and typical of the NSAID class, some have an idiosyncratic sensitivity that results in hepatic and/or gastrointestinal toxicity and, in extreme cases, death. As a result, NSAID label language contains bolded warnings and specifies that baseline blood tests should be conducted, and pets should be periodically monitored using blood tests to check for any toxic effects. Additionally, cats appear to metabolize NSAIDs differently than dogs, resulting in more severe side effects. Rimadyl is not approved for use in cats and no other Coxibs are approved in the U.S. for more than three days of use in cats.



# FIGURE 6. NSAIDS Used in Cats/Dogs

Drug	Subclass	Dose Form	Approved Indications	Dose	Comments
		Caplets	Pain and inflammation associated with osteoarthritis	4.4 mg kg <sup>-1</sup> PO, once daily	
Carprofen	Propionic acid	Chewable tablets	Pain associated with soft-tissue or orthopedic surgery	2.2 mg kg <sup>-1</sup> PO, twice daily	Safety not evaluated in dogs < 6 weeks of age
		Injectable		4.4 mg kg <sup>-1</sup> SC	
Deracoxib			Pain and inflammation associated with osteoarthritis	Osteoarthritis: 1-2 mg kg <sup>-1</sup> PO, once daily	Safety not evaluated in dogs < 4 months of age
Deramaxx	Coxib	Chewable tablets	Postoperative pain and inflammation associated with	Postoperative: 3-4 mg kg <sup>-1</sup> PO, once daily	
(Novartis)			orthopedic surgery	(7 day limit)	
Etodolac Etogesic (Fort Dodge)	Pyranocarboxylic acid	Tablets	Pain and inflammation associated with osteoarthritis	10-15 mg kg <sup>-1</sup> PO, once daily	Safety not evaluated in dogs < 12 months of age
Fircoxib Previcox (Merial)	Coxib	Chewable tablets	Pain and inflammation associated with osteoarthritis	5 mg kg <sup>-1</sup> PO, once daily	Use of this product at doses above the recommended 5 mg kg <sup>-1</sup> in puppies < 7 months of age has been associated with serious adverse
			Pain associated with soft-tissue surgery and orthopedic surgery		reactions including death
Mavacoxib Trocoxil (Pfizer Animal Health)- Non-USA	Coxib	Chewable tablets	Pain and inflammation associated with degenerative joint disease in cases where continuous treatment exceeding one month is indicated	2 mg kg <sup>-1</sup> PO Days 1, 14, 30 days then once monthly	Do not exceed 6.5 months duration of continuous therapy
Meloxicam Metacam (Boehringer Ingelheim)	Oxicam	Oral suspension	Pain and inflammation associated with osteoarthritis	0.2 mg kg <sup>-1</sup> PO (Injectable SC/IV) on day 1, then 0.1 kg-1 PO once daily	Safety not evaluated in dogs < 6 months of age
ingemenn)		Injectable			
Phenylbutazone (Various Manufacturers)	Pyrazolone derivative	Tablets	Relief of inflammatory conditions associated with the musculoskeletal system	3 mg kg <sup>-1</sup> (max 800 mg per 24 hours) PO every 8 hours. Maintain the lowest dose capable of producing the desired clinical response	No age related safety information reported
Animai Health)-	Onisor (Novartis		Treatment of pain and inflammation associated with cute musculoskeletal disorders	1 mg kg <sup>-1</sup> PO, once daily	Do not administer with food. The safety has not been evaluated in dogs < 2.5lg (5.5 lbs) or, < 3 months of age
Non-USA			Treatment of pain and inflammation associated with orthopedic or soft tissue surgery		months of age
Tepoxalin Zubrin TM (Schering- Ploug)	Hydroxamic acid derivative	Tablets	Pain and inflammation associated with osteoarthritis	10 or 20 mg kg <sup>-1</sup> on day 1, then 10 mg kg-1 once daily	Safety not evaluated in dogs < 6 months of age

Source: Veterinary Anesthesia and Analgesia; JMP Securities LLC

NSAIDs are well known to cause GI adverse events indirectly through the inhibition of PGE2 and directly by irritating the GI mucosa. High concentrations of NSAIDs in the gastrointestinal tract after oral administration, or due to biliary secretion, also contributes to the direct irritant effects of NSAIDs in the GI tract. Both COX-1 and COX-2 are constitutively expressed in the canine GI tract and the inhibition of these enzymes can lead to GI adverse effects. This limits the number of days per year that an animal can be treated with this class of drugs. The most common side-effects are:

- Loss of appetite
- Vomiting
- Diarrhea
- Increase in thirst
- Increase in urination
- Fatigue and/or Lethargy
- Loss of coordination
- Seizures



Rimadyl remains the leading prescription treatment with 40% market share.

# Market Opportunity in Pet Pain Management According to the April 2012 Brakke Consulting Pain

According to the April 2012 Brakke Consulting Pain Management Products Survey, the U.S. cat and dog analgesic market in 2011 was approximately \$260 million and consisted mostly of NSAIDs with sales of approximately \$220 million. Based on Aratana's estimates, the worldwide market for NSAIDs exceeded \$450 million in 2012. According to a survey of 233 veterinarians conducted by Brakke Consulting in March 2012, veterinarians recommended NSAID therapy for 82% of the dogs they treated with osteoarthritis, and they believe ~60% receive treatment. The Market Dynamic Inc. sales audit data shows that over four million dogs annually are receiving an average of 20 days of treatment with NSAID therapy. The NSAID segment is one of the fastest growing categories in pet therapeutics over the past fifteen years; it continued to expand with four additional NSAID Coxib approvals and the approval of the first of five generic carprofen products starting in 2005. Rimadyl remains the leading prescription treatment, with 2011 U.S. sales of \$90 million and a 40% market share. According to Brakke, sales of generic carprofen were \$20 million, or 9% market share, in 2011, up 25% from 2010.

Given the associated side effects and required monitoring with blood tests that are associated with NSAID therapy, there is a population of dogs that remains untreated or cannot be treated chronically. Additionally, while up to 30% of cats over the age of ten have osteoarthritis, currently available products in the United States cannot be used to treat cats for chronic pain associated with osteoarthritis. This implies a significant market opportunity for a therapeutic product that can manage the pain and inflammation associated with osteoarthritis in pets with an improved safety profile that does not require regular blood monitoring.

## AT-001 is an EP4 receptor antagonist

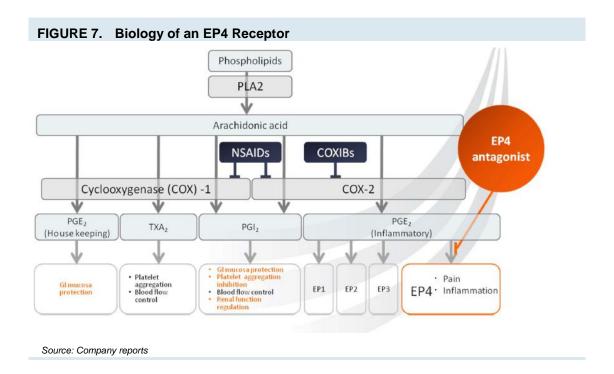
Unlike Coxib NSAIDs, AT-001 is a selective EP4 receptor antagonist. EP4 is one of four G-protein coupled PGE<sub>2</sub> receptors (EP1, EP2, EP3, and EP4) located on the membrane of various cells in the mammalian body. The EP4 receptor predominantly mediates PGE<sub>2</sub>-elicited pain. The specific effects of the binding of PGE<sub>2</sub> to the EP4 receptor include vasodilation, increased permeability, angiogenesis, and production of pro-inflammatory mediators. The EP4 receptor mediates PGE<sub>2</sub>-elicited sensitization of sensory neurons and studies have demonstrated that EP4 is a major receptor in mediating pain associated with rheumatoid arthritis, osteoarthritis, and inflammation. EP4 knockout mice, mice that have been genetically manipulated not to express the EP4 receptor, but not EP1, EP2, or EP3 receptors, have exhibited decreased inflammation and decreased incidence and severity of disease in experimental models of arthritis.

As shown in the Figure 4, a selective EP4 receptor antagonist does not interfere with EP1, EP2, or EP3 receptor-mediated signaling, and does not affect prostaglandin biosynthesis, which is important for the maintenance of the gastrointestinal, renal, and platelet function. Unlike Coxib NSAIDs, an EP4 receptor antagonist does not change prostanoid homeostasis. Treatment with Coxib-type drugs can result in a PGI/TXA2 imbalance, which is postulated as the cause of cardiovascular side-effects of this drug class.

AT-001 binds selectively to the EP4 receptor with high affinity, thus blocking it from  $PGE_2$ -mediated pain and inflammation. The human, rat, dog, and cat EP4 receptor genes were cloned and showed significant homology. In receptor binding studies, the inhibitor constants, or Ki value, of AT-001 for human, rat, and dog receptors were determined, indicating that AT-001 binds to the receptor with high affinity. Ki value reflects the concentration of inhibitor that is required to decrease the maximal rate of the reaction to half of the uninhibited value.

EP4 is one of four G-protein coupled PGE<sub>2</sub> receptors (EP1, EP2, EP3, and EP4) located on the membrane of various cells in the mammalian body





AT-001 has achieved proof of concept in two Phase II clinical trials performed by RaQualia in humans with osteoarthritis knee pain. The trials included patients who received AT-001, Naproxen, an NSAID, or placebo. More than 500 human patients were dosed with the compound. The compound was well-tolerated and demonstrated statistically significant reduction in pain scores as compared to placebo. Based on the results generated with the compound by RaQualia in humans, Aratana believes that selective antagonism of the EP4 receptor should have fewer drug side effects and similar efficacy as compared to Coxib NSAIDs in cats and dogs.

### AT-001 in dogs

<u>Safety.</u> In the toxicology program that was conducted by RaQualia to support human drug development, a series of studies investigated the effects of oral administration of AT-001 to male and female laboratory dogs. Aratana intends to use the results from a nine-month GLP toxicology study of oral AT-001 given daily as the pivotal study to be submitted to regulatory authorities to demonstrate target animal safety in dogs. The nine-month GLP toxicology study was undertaken to evaluate the potential toxicity and systemic exposure of AT-001 when administered orally, once daily, for nine consecutive months to dogs and to assess the reversibility of any toxic changes.

In the study, AT-001 was administered orally once daily at doses from 0 to 50 mg/kg. A total of 36 dogs were evaluated in four dose groups, with each dose group consisting of four male and four female dogs. Four additional dogs, two male and two female, were evaluated in the 50 mg/kg dose group for recovery purposes. Clinical signs and food consumption were assessed daily. Body weight was recorded weekly. Ophthalmologic examinations, electrocardiograms, hematology, serum chemistry, and urinalyses were monitored periodically. In the high dose group only, serum drug concentrations of AT-001 were measured at several time points after dosing on day 1 and on a single day in week 38. At the end of the dosing or recovery period, dogs were necropsied and further examined.



The study demonstrated no drug-related effects on body weight, food consumption, ophthalmology, electrocardiograms, hematology, coagulation, organ weights, and gross pathological findings during the nine-month dosing period. Gastrointestinal effects such as loose or mucous stool, which sometimes included slight bloody or red material, were observed in all dose groups including the control, though the incidence was higher in some animals of the drug groups compared with that in the control group. A significant decrease in mean serum albumin was observed at weeks 26 and 39 in the highest dose group (50 mg/kg). The serum parameter changes had improved at the end of the recovery period. There were no noteworthy findings during, or at the end of, the four-week recovery period.

In addition to the results from the nine-month study, Aratana's data safety package will also include a pharmacokinetic study that bridges from the formulation used in the toxicity study to the final commercial tablet formulation. The protocol of the pharmacokinetic bridging study will be submitted to the CVM for review and concurrence. We believe this data package will be acceptable to the CVM to complete the target animal safety section of the NADA for AT-001.

Effectiveness. Aratana performed initial proof of concept studies in laboratory dogs with artificially induced osteoarthritis. Management believes these studies signaled that the compound is effective, though the variability and the small group sizes limited the power of the results. Consequently, the company has commenced another study to confirm efficacy and select a dose. This study is a multisite, randomized, blinded field study in client-owned pets with osteoarthritis. The study is designed to enroll over 300 dogs across four treatment arms including three different AT-001 treatment regimens and a placebo. Effectiveness in the study is being determined by using a validated pain scoring system. The CVM has reviewed the study protocol and concurred with the design. Aratana launched the study in February 2013 and expect it to be completed in late 2013. Upon completion of the study, the company will discuss with the CVM if, and what, further data will be required to complete the effectiveness requirements.

Chemistry, Manufacturing, and Controls (CMC). Aratana has engaged a contract manufacturer for the API process development and a specialized animal health contract manufacturer as the contract laboratory to make the formulated product. Both API and formulated product are manufactured according to current Good Manufacturing Practices, or cGMP, standards. The company is developing a process according to standards from the International Conference on Harmonization (ICH) that can be used to supply both human and veterinary development and commercialization. The company has selected a final formulation of AT-001, and produced clinical trial material. The API contract manufacturer has developed the chemical synthesis and process to a multi-kilogram batch size and is continuing to refine the process.

Aratana expects its NADA approval in 2016

Development Plan. Aratana plans to complete its ongoing dose confirmation efficacy study, at which point the company will be able to evaluate, together with the CVM, whether additional effectiveness data will be required to support the company's New Animal Drug Application (NADA). If more data are needed, Aratana anticipates using the same concurred study design for an additional pivotal effectiveness trial. Concurrently, Aratana continues to develop and refine its CMC data package. Aratana plans to have the three major technical sections of the NADA for AT-001 complete by the end of 2015 and, assuming the company achieves that goal and the submission is acceptable, Aratana would expect NADA approval in 2016 (Figure 11). The company's European regulatory strategy tracks that of the United States. Management believes that data provided for its NADA filing in the U.S. should largely satisfy EMA requirements. Aratana is currently evaluating any gaps that may exist and expects to address those differences with human safety risk assessment, dose determination, and expert opinion reports. Aratana believes it could achieve EMA approval in 2017.



FIGURE 8. AT-001 Development Schedule/Timeline



Source: Company reports, JMP Securities LLC

#### AT-001 in cats

<u>Safety.</u> Aratana has conducted a number of laboratory probe studies to test the safety of AT-001 in cats. A 28-day safety study in 24 normal, healthy cats suggests that AT-001 is well tolerated at levels representing multiples of the potential therapeutic dose for up to 28 days. The company also evaluated the safety of AT-001 in cats in post-operative settings. Under these conditions, Aratana observed a dose-dependent increase of blood parameters related to liver metabolism, which is a signal of potential liver toxicity. Study results demonstrate that this observation is a combined effect of the medication used to produce general anesthesia and high AT-001 dosages. The study also showed that these effects were reversible and there were no abnormal clinical findings. While the company cannot rely on any of these initial studies as pivotal safety studies, consistent with FDA requirements, the company will include the results of these studies in its NADA as additional information.

<u>Development plan.</u> Aratana continues to evaluate the appropriate indication for the use of AT-001 in cats. The next steps include additional safety studies in laboratory cats, outlining a development plan, including possible label claims for cats, and a meeting with the CVM to review this plan. The CMC process for AT-001 in cats is expected to be similar to that for AT-001 in dogs.

## **Market Opportunity Projections: AT-001**

Our market projections for AT-001 model its use in the treatment of osteoarthritis in dogs and in the treatment of post-surgical pain in cats. For the indication of osteoarthritis in dogs, we assume a market launch of AT-001 beginning in 4Q15 in the U.S. and a steady market share growth within ten years from <2% share of total market in 2016 to 15% in 2025. Market launch in Europe is anticipated to begin in 4Q16 with incremental market penetration and a steady climb in market share from 1.4% in 2017 to 15.0% in 2025.

For the indication of post-surgical pain in cats, we assume a market launch of AT-001 beginning in 2016 in the U.S. and Aratana's share of the total surgical market to peak at ~50% within five years. Market launch in Europe is expected to begin in 2017 and we assume Aratana's market shares will peak at ~50% within five years.

As such, we project revenues from the U.S. and Europe within their respective timeframe for each indication. Key projections and modeling assumptions are outlined in Figures 9 and 10 and a summary of our revenue projections for AT-001 is highlighted in Figure 11.



FIGURE 9. Revenue Assumptions, AT-001 for Osteoarthritis in Dogs

Number of Dogs in the US	78.2 million
Number of Dogs in the EU	60.2 million
Dogs that Regularly Receive Care from veterinarion	85%
Incidence of OA in Dogs	20%
Dogs with OA Receiving NSAID Treatment (US)	60%
Dogs Receiving NSAID Treatment (EU)	40%
Average Days of Therapy for NSAID Treatment	30
Average Daily Cost of Therapy for NSAID Treatment	~\$1.00/day
AT001 Average Days of Therapy	45
AT001 Average Daily Cost of Therapy to Veterinarian	\$1.25/day
Aratana Peak Market Share	15%

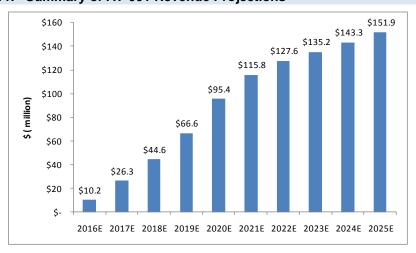
Source: Company reports, JMP Securities LLC

FIGURE 10. Revenue Assumptions, AT-001 for Post-Surgical Pain in Cats

Number of Felines in the US	86.4 million
Number of Felines in the EU	64.4 million
Estimated # of surgeries performed on cats annually in US	14.1 million
Estimated # of surgeries performed on cats annually in EU	7.6 million
Percent of Cats Receiving Perioperative Pain Medication	80%
Average Days of Therapy for AT- 001	5
Daily Cost of Therapy to Veterinarian for AT-001 20mg tablet	\$1.00
Aratana Peak Market Share (of total surgical market)	50%
Year to Peak Sales	5

Source: Company reports, JMP Securities LLC

FIGURE 11. Summary of AT-001 Revenue Projections



Source: JMP Securities LLC Estimates



# AT-002 FOR INAPPETANCE (LACK OF APPETITE)

AT-002 (capromorelin) is a potent and selective ghrelin agonist, which causes appetite stimulation and growth hormone secretion. AT-002 was originally discovered by Pfizer and achieved proof of concept in Phase II clinical trials in humans. Aratana in-licensed AT-002 from RaQualia Pharma, which is investigating the use of AT-002 in human medicine. Aratana is developing AT-002 for the stimulation of appetite in cats and dogs. AT-002 is in the dose characterization and confirmation phase.

## **Medical Need: Inappetance**

The control of hunger and satiety involves a complex system in mammals. In many acute and chronic disease states, as well as with aging, lack of appetite is a problem and can fuel a downward spiral. Malnutrition and decreased muscle mass can result from inadequate food intake regardless of the underlying condition. In humans, doctors can rationalize with patients the importance of maintaining nutrition despite the lack of natural appetite and there are medical therapeutics approved in humans to treat inappetance. Veterinarians and pet owners cannot successfully rationalize with pets about the importance of maintaining nutrition and there are no approved medical therapeutics to treat inappetance in pets. This can be a frustrating clinical situation for the veterinarian and pet owner and often contributes to the decision to euthanize a pet.

Fear, pain, stress, trauma, organic disease, dental disease, oral fractures, and cancer are all possible causes of inappetance in pets. For example, inappetance commonly occurs in conjunction with chronic renal failure (CRF). Dietary therapy with a diet designed for cats and dogs with renal insufficiency is recommended, regardless of the severity of disease. Unfortunately many therapeutic diets that are prescribed may be less palatable to pets than normal diets. For pets undergoing cancer treatment, the cancer therapy must be stopped when the pet loses appetite and body weight. In other instances, lack of appetite, particularly in cats, can result in hepatic lipidosis. Hepatic lipidosis is the most common liver disease in cats and progressive accumulation of hepatic fat without treatment to increase food intake can lead to death.

## **Currently Available Treatments and Limitations**

The first goal of therapy for inappetance is to correct the underlying cause. Most often veterinarians will begin treatment of inappetance by recommending a change to a highly palatable diet such as tuna for cats and chicken or beef for dogs. Depending on the severity of the condition, the animal may be supported with fluids and electrolytes until the diagnosis of the underlying condition is made and effective treatment is initiated where possible. Prolonged or severe inappetance may require hospitalization and feeding tube placement. There are no drugs approved for the treatment of inappetance in cats and dogs. Drug therapy to address inappetance has focused on human drugs affecting the central nervous system control of feeding such as benzodiazapines, cyproheptadine and mirtazapine. However, these drugs are not approved for veterinary use, have limited effectiveness and are contraindicated for cats with hepatic lipodosis. As a result, there is a significant market opportunity for a therapeutic product that is safe and can effectively stimulate appetite in pets.



AT-002 is a potent and selective ghrelin agonist

# AT-002 is a Ghrelin Agonist

AT-002 is a potent and selective ghrelin agonist. Ghrelin is a 28-amino acid peptide hormone, also referred to as the hunger hormone, produced predominantly in the stomach. It is the endogenous ligand of the ghrelin receptor, (i.e., growth hormone secretagogue receptor (GHS-R)). By activation of the ghrelin receptor, ghrelin stimulates appetite and growth hormone secretion, and also exhibits a role in the regulation of gastrointestinal motility and energy balance. As depicted in Figure 12, ghrelin binds to specific receptors and affects signaling in the hypothalamus, interacting with other hormones to cause the feeling of hunger and stimulate food intake. In addition to its effects on appetite, ghrelin stimulates growth hormone secretion by activation of GHS-Rs in the pituitary. This effect acts to build lean body mass, which has been shown to result in increased strength in frail, elderly people.

Brain Increase in appetite Pituitary gland O Growth Hormone secretion o Increase in appetite Growth Ghrelin Hormone Ghrelin (GH) Stomach Energy metabolic regulation Stimulates metabolic product of lean body mass Intestine

FIGURE 12. Biology of Ghrelin

Source: Company reports

AT-002 is a small molecule that mimics ghrelin and binds to the GHS-R. The appetite stimulation and GH-releasing activity of AT-002 has been demonstrated in laboratory cats and dogs where AT-002 treatment results in increased food intake and weight gain. Similarly, chronic oral dosing of AT-002 in a canine GLP toxicology study stimulated appetite and weight gain and caused increased plasma growth hormone levels. The initial human development focus for AT-002 at Pfizer was on frailty, congestive heart failure, and fibromyalgia. More than 1,200 human subjects have participated in Phase I and Phase II clinical trials involving AT-002 and the drug was shown to be generally safe in humans. Two of the most commonly reported adverse events in humans were increased appetite and weight gain, which the company believes support its intended development for inappetance in pets.



# AT-002 in Dogs

**Safety.** In the toxicology program that was conducted to support the filing of an investigational new drug application, or IND, for human drug development, a series of studies investigated the effects of oral once daily administration of the compound to male and female dogs. Aratana intends to use the results from a dog GLP 12-month toxicology study as the pivotal safety data to be submitted to the regulatory authorities to demonstrate safety in dogs. In the study, AT-002 was administered orally once daily at doses from 0 to 40 mg/kg for 12 consecutive months. A total of 32 dogs were evaluated in four dose groups, with each dose group consisting of four male and four female dogs. All animals were observed daily for clinical signs and received periodic ophthalmology examinations, physical examinations, including vital signs and blood pressure monitoring, electrocardiograms, and clinical pathology evaluations.

At the end of the dosing period, dogs were necropsied and further examined. Clinical signs related to the administration of AT-002 were limited to salivation in the high dose groups and loose stool seen sporadically at all dose levels, including controls. Occasional episodes of vomiting were observed throughout the study, but were considered unrelated to treatment. Ataxia, or lack of muscle coordination, was observed on one occasion in one intermediate dose dog. One dog died during the dosing period as a result of accidental delivery of drug into the respiratory tract. There were no treatment-related effects noted on ophthalmology and physical examination. Electrocardiogram changes were observed in the high and intermediate dose groups one to two hours following dosing. Hematology and urinalysis results were considered to be within normal range and unaffected by treatment with AT-002. Serum alkaline phosphatase was increased in the high dose treatment group.

Other treatment-related changes within the high dose AT-002 group included increased cholesterol and HDL associated with accelerated lipolysis. All other serum chemistry results were either within normal ranges or lacked consistent dose/time relationship. Necropsy results revealed no treatment-related macroscopic findings and no histological lesions were observed in the heart. Treatment-related adverse events observed at the highest doses were limited to gastrointestinal, cardiovascular, and hepatic systems. Based on this study, Aratana believes that AT-002 could be well tolerated in dogs and, depending on the final approved dose, could demonstrate up to a 10x safety margin. In addition to the results from this 12-month study, the company's data safety package will include a pharmacokinetic study that bridges the formulation used in this toxicity study to the final commercial formulation.

<u>Effectiveness.</u> Several laboratory studies in healthy dogs with various daily oral doses of AT-002 for four to ten days were completed prior to the licensing of AT-002. These studies demonstrated increased food intake and weight gain. Aratana conducted a seven-day, placebo-controlled, blinded-dosing study in dogs to confirm these results, and confirmed that treated dogs showed a sustained increase in appetite and body weight over the treatment period, with the placebo-control treated dogs losing weight, likely due to intensive handling and blood sampling.

The company evaluated the effectiveness of AT-002 compared to placebo for the treatment of inappetance in a pilot placebo-controlled, blinded, multi-veterinary clinic field study in client-owned patients. The study was designed to evaluate the effectiveness of the drug in client-owned dogs, as opposed to laboratory animals, to test the acceptance of the formulation, ease of dosing, and appetite assessments by owners, and to define the patient population.



Effectiveness parameters included owner assessment of appetite and body weight gain, compared to baseline and to the dog's best lifetime condition. Dogs were treated once daily for seven days. The results of 30 evaluable cases are shown in the table below. Compared to the placebo-control animals, the appetite score and body weight of the AT-002 treated patients were statistically significantly increased on day 6 after seven daily treatments. The results compared to best lifetime condition showed a positive trend towards the AT-002 treatment, but were not statistically significant.

FIGURE 13. Summary Table of AT-002: Results of 30 Evaluable Cases

Group	Appetite Sco	ore on Day 6		Body Weigh	nt on Day 6
	% Change	% Change		% Change	
	mean/SEM	p-value		mean/SEM	p-value
AT-002 (n=17)	79/19	< 0.05		3.3/1.2	< 0.05
Placebo (n=13)	20/12			-0.2/0.9	

Note: p-value ≤ 0.05 indicated statistical significance on a 95% or higher confidence level

Source: Company reports, JMP Securities LLC

Chemistry, Manufacturing and Controls (CMC). When Aratana licensed the drug, the chemical process was scaled up to kilogram quantities, but was not optimized. The company's contract manufacturer for the API process development is developing a process according to ICH standards that can be used to supply both human and veterinary development and commercialization. Aratana has successfully completed process development of AT-002, with three cGMP batches manufactured and API shipped for manufacture of clinical trial material. As with AT-001, Aratana is using an animal health specialty contract manufacturer to develop the formulation according to CVM and EMA standards. The manufacture and release of the first cGMP batch of formulated product that will be used as clinical trial material is expected in mid-2013.

Aratana expects to receive NADA approval on AT-002 by the end of 2015.

<u>Development plan</u>. Aratana has prepared a detailed development plan for AT-002 in dogs and has scheduled a meeting to present that plan to the CVM, where the company expects to agree on the pivotal data that will be required for the NADA. Its development plan includes the submission of the 12-month dog GLP toxicology data, together with the pharmacokinetic bridging study, to satisfy the required pivotal safety data. Aratana plans to continue the ongoing field effectiveness study in client-owned dogs until the company meets its enrollment target, at which point Aratana plans to use the data from that study to design a pivotal field effectiveness study. The pivotal field effectiveness study protocol will be submitted to the CVM for concurrence, and Aratana expects to commence the pivotal field effectiveness study in the second half of 2013.

Concurrently, Aratana continues to develop its CMC data package and plans to have a pre-submission meeting with the CVM to discuss CMC in mid-2013. Further, Aratana plans to have all three major technical sections of the NADA completed in time to receive NADA approval by the end of 2015 (Figure 13). On the European regulatory front, Aratana expects data provided for its NADA filing in the U.S. to largely satisfy the EMA requirements. The company is currently evaluating any gaps that may exist and expects to address those differences with human safety risk assessment, dose determination, and expert opinion reports.



FIGURE 14. AT-002 Development Timeline

AT-002 (Inappetence)	2012	2013	2014	2015	2016	2017	
Formulation							
Proof-of-Concept: Dog		$\rightarrow$					
Proof-of-Concept: Cat		<b>—</b>					
Clinical Safety			<b></b>				
Pivot Field Trial			$\rightarrow$				
CMC Package				$\longrightarrow$			

Source: Company reports, JMP Securities LLC

#### AT-002 in Cats

**Safety.** When Aratana licensed AT-002, included in the data was a two-week safety study in cats. Because the company expects the potential patient population for AT-002 to include elderly cats suffering from chronic renal failure, it tested the safety of AT-002 in a model of kidney compromised laboratory cats. The results from the two-week study in normal cats suggested that AT-002 was well tolerated. The results from the safety study in kidney compromised cats also demonstrated no treatment related side effects. Based on these studies, Aratana believes the company has demonstrated that AT-002 has a favorable safety profile in cats and expects that sufficient safety margins will be seen in the pivotal safety study.

**Effectiveness.** Several laboratory studies in healthy cats using various daily AT-002 oral doses were also included in the data package at licensing. Food intake and weight gain were increased after administration of AT-002 to cats. The company confirmed these results by conducting a 10-day laboratory study in cats, the results of which demonstrated the desired physiological hormone effects from AT-002 treatment. The company is currently conducting a dose confirmation study to determine the appropriate dose for its pivotal field effectiveness field study. This study will evaluate client-owned cats and is designed to confirm that AT-002 causes increased appetite and weight gain in cats and to evaluate the acceptance of the formulation and dosing by owners. The study design is similar to that of the pilot study for AT-002 in dogs. This study began in January 2013 and enrollment is continuing. Aratana expects to report the results from this study in mid-2013.

**Chemistry, Manufacturing and Controls (CMC)**. Aratana expects CMC for AT-002 for cats to follow a similar process to that described above for AT-002 in dogs.

**Development plan.** Aratana is preparing its detailed development plan for AT-002 in cats and intends to present that plan to the CVM in late 2013, when it expects to agree on pivotal data that will be required for the NADA. Its development plan includes a standard safety study in cats, according to CVM guidelines to meet the safety requirements. Further, Aratana plans to continue the ongoing study in client-owned cats and will use the results of that study to design the required pivotal field effectiveness study. The company expects to submit the pivotal field effectiveness study protocol to the CVM for concurrence.

In the meantime, the company continues to develop its CMC data package and plan to have a presubmission meeting with the CVM to discuss CMC at the appropriate time. Aratana plans to have all three major technical sections of the NADA completed by the beginning of 2016, followed by an anticipated NADA approval within a year (Figure 14).



## **Market Opportunity Projections: AT-002**

Our market projections for AT-002 model its use in the treatment of inappetance in dogs diagnosed with cancer and cats diagnosed with chronic kidney disease (CKD). For the indication of appetance in dogs, we assume a market launch of AT-002 beginning in 2006 in the U.S. with incremental market share growth from <10% share of total market in 2006 to 45% in 2024 and beyond. Market launch in Europe in anticipated to begin in 2017 with significant market penetration in the first few years and market share gains from 2% in 2017 to 45.0% in 2025. For the indication of appetance in cats, we assume a market launch of AT-002 beginning in 2006 in the U.S. and Aratana's share of the total market to grow over time and peak at ~40% within eight years (i.e., 2024). Market launch in Europe is expected to start in 2017, and we assume Aratana's market shares will peak at ~40% in 2014.

As such, we project revenues from the U.S. and Europe within their respective timeframe for the indication of dogs and cats. Key projections and modeling assumptions are outlined in Figures 15 and 16, and a summary of the total revenue opportunities for AT-002 is highlighted in Figure 17.

FIGURE 15. AT-002 Revenue Assumptions: Inappetance in Dogs Diagnosed with Cancer

Number of Dogs in the US	78.2 million
Number of Dogs in the EU	60.2 million
Percent of Dogs receiving veterinary care (US)	85%
Percent of Dogs receiving veterinary care (EU)	85%
Cancer:	
Incidence of Cancer in Dogs	2.1%
Percent of Dogs with Cancer that Receive Treatment	61%
Percent of Dogs with Cancer that Receive Chemo	58%
Average Days of Treatment for Dogs with Cancer	125
Treatments per day	1
Cost per Treatment	\$2.00
Aratana Market Share	45%

Source: Company reports, JMP Securities LLC

FIGURE 16. AT-002 Revenue Assumptions: Inappetance in Cats with Chronic Kidney Disease (CKD)

Number of Cats in the US	86.4 million
Number of Cats in the EU	64.4 million
Percent of Cats Receiving Regular Veterinary Care (US)	66%
Percent of Cats Receiving Regular Veterinary Care (EU)	66%
CKD:	
Incidence of CKD in Cats	1.6%
Cats with CKD with reduced appetite	30.0%
Average Days of Therapy for AT002	90
Treatments per day	1
Daily cost of therapy	2
Aratana Peak Market Share	40%

Source: Company reports, JMP Securities LLC







Source: JMP Securities LLC Estimates



Aratana intends to develop AT-003 as a therapeutic to manage post-operative pain in cats and dogs following surgery.

### AT-003 FOR POST-OPERATIVE PAIN

AT-003 is a bupivacaine liposome injectable suspension that Aratana in-licensed from Pacira. The product was approved for use in humans as a local, post-operative analgesic by the FDA in October 2011 and is marketed by Pacira under the name EXPAREL for use in controlling post-operative surgical wound pain following various types of surgical procedures. Aratana intends to develop AT-003 as a therapeutic to manage post-operative pain in cats and dogs following surgery. Aratana expects to use the same product in both species.

### Medical need: Post-operative Pain

Veterinarians perform ~ 19 million dog surgeries and 14 million cat surgeries each year that range from routine spays and castrations to orthopedic cruciate repairs and fracture repairs. Approximately 50% of dog surgeries and 58% of cat surgeries, respectively, are spays and neuters. There is no established protocol for the use of pain medications in these surgeries and pain management practices have traditionally been based on the veterinarian's views on the level of pain associated with a specific surgical procedure and the perceived pain tolerance of the pets. Recently, as pet owners have begun requesting analgesia for their pets' painful conditions, veterinarians have made advances in treating pain in pets. Moreover, animal research demonstrates that pain can have a detrimental effect on healing, and pain experts in academia and specialty clinics are advocating more use of local anesthesia for pain control.

# **Currently Available Treatments and Limitations**

The only drugs approved for treatment of post-operative pain in cats and dogs are Coxib NSAIDs and fentanyl. The same group of NSAIDs approved to treat the pain and inflammation associated with osteoarthritis in dogs are used for post-operative pain. Some of these drugs can be given in the veterinary hospital as an injection, and then dispensed to the owner for a few days of treatment at home. For cats, only two NSAIDs are approved by the CVM for use in post-operative pain. These are Onsior, which is given orally and is approved for no more than three days of use, and Metacam, which is approved for one injectable dose only.

Among the drugs used for post-operative pain, some have been approved by the CVM and some are used off label. The most commonly used post-operative pain medication in dogs is Rimadyl, which has been approved by the CVM for this use. The most common product for post-operative pain in cats is buprenorphine; however, this drug is not CVM-approved for this use. As previously described in the discussion regarding AT-001 for dogs, NSAIDs have demonstrated significant side effects that result in prescribed monitoring of dog health during use. For example, some dogs have an idiosyncratic sensitivity that results in hepatic toxicity and, in extreme cases, death. Consequently, veterinarians would appreciate a drug that was effective, but also safer on the liver, gastrointestinal system, and kidneys for post-operative use.



# AT-003 is a 1.3% bupivacaine injectible

AT-003 is a 1.3% bupivacaine liposome injectable suspension. It consists of microscopic, spherical multivesicular liposomes, which is Pacira's proprietary DepoFoam drug delivery system. Bupivacaine is released from the DepoFoam particles by mechanisms involving reorganization of the barrier lipid membranes and subsequent diffusion of the drug occurs over an extended period of time. The formulation has been shown to extend the duration of human post-operative analgesia from approximately six to eight hours, to as long as 72 hours in some instances, which can eliminate the need for follow-on, post-operative administration of other pain drugs. Additionally, the slower uptake of the bupivacaine into the systemic circulation helps avoid high plasma concentration and presumably lowers the risk of systemic toxicity.

Bupivacaine is a local anesthetic that prevents the generation and conduction of nerve impulses, apparently by increasing the threshold for electrical excitation in the nerve, by slowing the propagation of the nerve impulse, and by reducing the rate of rise in the action potential. Bupivacaine has a history of use in the United States of more than 30 years and its pharmacology, pharmacodynamics, and toxicology in laboratory animals and humans are well understood. Bupivacaine is widely used by veterinary surgeons.

## Human clinical results from AT-003 human development program

EXPAREL has demonstrated efficacy and safety in two multicenter, randomized, double-blind, placebo-controlled, pivotal Phase III clinical trials in humans undergoing soft tissue surgery and orthopedic surgery. Both trials met the primary efficacy endpoints in demonstrating statistically significant analgesia through 72 hours for the tissue surgery trial and 24 hours for the orthopedic surgery trial. Both trials also met multiple secondary endpoints, including decreased opioid use and delayed time to first opioid use. These two pivotal Phase III clinical trials formed the basis of the evidence for efficacy in the FDA-approved NDA for EXPAREL.

The safety of EXPAREL has been demonstrated in 21 clinical trials in humans consisting of nine Phase I clinical trials, seven Phase II clinical trials and five Phase III clinical trials. EXPAREL was administered to over 1,300 human patients at doses ranging from 10 mg to 750 mg administered by local infiltration into the surgical wound and by subcutaneous, perineural, epidural, and intraarticular administration. In all 21 clinical trials, EXPAREL was well-tolerated.



# AT-003 in cats and dogs

**Safety.** Pacira conducted an extensive toxicology program to support human drug development. Both the liposome formulation alone and the bupivacaine-formulated product underwent extensive *in vitro* and *in vivo* safety testing, which included numerous studies performed in laboratory dogs. As a result, Aratana has seven studies that it plans to use to support approval for AT-003 in dogs. The company believes its pivotal dog safety study for AT-003 is the subcutaneous toxicity study with twice-weekly dosing for four weeks in dogs that was conducted as part of the human development program.

The study was conducted to evaluate potential local and systemic toxicity of twice-weekly subcutaneous dosing for four weeks. Also, the reversibility, progression or delayed appearance of any observed changes were evaluated in a four-week post-dose observation period. A total of 60 dogs were allotted to five groups of six male and six female dogs. Three groups were treated twice weekly with EXPAREL at different dose levels, one group with bupivacaine HCl injection, also known as Sensorcaine, and one group with normal saline. After the four-week dosing period, three male and three female dogs per group were maintained for a 28-day recovery period. All animals were observed daily for clinical signs. Clinical examinations and body weight measurements were performed weekly. Electrocardiograms, hematology, serum chemistry, and urinalyses were monitored periodically.

At the end of terminal and recovery periods, necropsy examinations were performed, organ weights were recorded and selected tissues were microscopically examined. The only EXPAREL effects were associated with the injection sites in dogs. This effect was considered an expected response to the liposomes in EXPAREL and non-adverse because of the low incidence and severity observed in these dogs.

**Effectiveness.** To date, Aratana has not obtained any effectiveness data for the use of AT-003 in cats or dogs, although short-acting bupivacaine has been used extensively for short-term treatment of post-operative pain by veterinarians in cats and dogs. Given the proven clinical effectiveness of EXPAREL in humans, Aratana expects AT-003 will demonstrate extended post-operative analgesia in cats and dogs.

Chemistry, Manufacturing and Controls (CMC). Aratana intends to use the same product that was approved by the FDA for the AT-003 development program and expect to receive a CMC technical section complete letter based on the same data that was submitted to the FDA for the NDA of EXPAREL. The company plans to submit a full CMC package to the CVM for a full review.

Development plan. Aratana has established an investigational new animal drug (INAD) file with the

CVM. The company plans to schedule a pre-development plan meeting with the CVM to present and discuss an outline of its proposed development activities, including presentation to the CVM and agreement on the CMC submission plans. Aratana will also discuss the safety data to be submitted in support of the dog approval and will submit pivotal protocol for a standard target animal safety study in cats. Aratana plans to initiate dose confirmation studies in both cats and dogs late in 2013. After a dose regimen has been established, the company will submit to the CVM pivotal study protocols to demonstrate effectiveness in cats and dogs and anticipate filing its NADA for both cats and

Aratana plans to initiate dose confirmation studies in both cats and dogs late in late 2013.

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dogs in 2015.



## **COMMERCIAL STRATEGY**

The company is planning to pursue a multi-faceted commercial strategy. In the U.S., the company is likely to use a combination of direct sales, distributors, and corporate sales teams. Internationally, the company is like to use a distributor model until the brand becomes more established.

Direct sales – According to the AVMA there are almost 100,000 veterinarians in the U.S. However, a company of Aratana's size can effectively target high-value accounts (defined as practices with > \$1 million in annual revenue) with a sales force of 100 people. The company is likely to expand its commercial efforts once the three compounds in development are closer to approval, likely in 2015.

Distributors – The majority of the market is comprised of clinics that have less than \$1 million in revenue. To reach the vast majority of these clients, the company is likely to use a major distributor such as Henry Schein or MWI. The trade-off is that the company gives up gross margin in return for little or no SG&A expenses.

Corporate sales – Banfield and VCA Animal Hospitals are the two largest corporate "chain-store" like veterinary groups. Banfield operates over 800 clinics and VCA operates more than 500 clinics. Selling to these organizations requires a small team, perhaps just one or two people.

International strategy – The company is likely to partner with local distributors to market its therapies. This may change over time as the pipeline expands and the company's brand becomes more entrenched.

With regards to pricing, the company intends to price AT-001 at \$1.25/day vs. the current average of \$1.00 per day; veterinarians will mark this up by 100% to sell to clients. We assume AT-002 will be priced at \$2.00 per day. Since there are no other drugs approved for this indication, it is difficult to have a frame of reference by which to judge whether this price is too cheap or too expensive. However, our own primary research into the matter (see survey section) indicates solid demand at this price level.

## PROPRIETARY VETERINARY SURVEY

We surveyed a total of 50 veterinarians to explore a number of topics on veterinary practice, including overall revenue mix, the drugs typically prescribed to treat pets with osteoarthritis and inappetance, and the impact of the prescribed drugs on the medical condition of the pets.

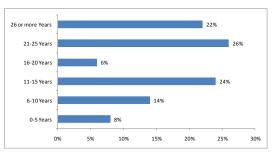
Of the 50 veterinarians surveyed, nearly half of them have over 20+ years of experience as practicing veterinarians. All of our respondents have treated cats and dogs in their practice. Overall, they treat a total of 1,225 cats and 2,177 dogs per year on average, and 186 cats with osteoarthritis and 578 dogs with osteoarthritis per year, on average.

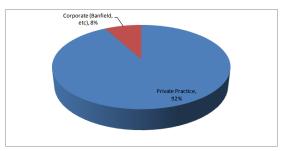
Approximately 92% of the respondents work in private practice, ~36% of the veterinarians surveyed generated between \$1 and \$1.25 million in sales and ~20% of the respondents had sales of > \$2.0 million in their practice in 2012. Annual Exams and Diagnostics are the two segments that contribute the most to the overall revenue mix with 19% and 18% of revenue, respectively, followed by Vaccinations and Surgery, with each contributing 15% of overall revenue.



FIGURE 18.Number of Years of Experience as a Practicing Veterinarian

FIGURE 19. Type of Veterinary Practice





Source: JMP Securities LLC

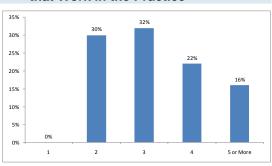
Source: JMP Securities LLC

FIGURE 20. Sales Generated from Practice in 2012

40% 35% - 30% - 25% - 20% - 16% 16% 12% - 10% - 5% - 0% - 16% 15% - 10% - 5% - 0% - 16% 15% - 10% - 5% - 0% - 10% - 5% - 0% - 10% -

Source: JMP Securities LLC

# FIGURE 21. Number of Veterinarians that Work in the Practice



Source: JMP Securities LLC

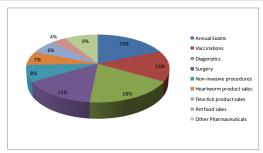
FIGURE 22. Geographic Representation

Alabama	Maryland
Arizona	Missouri
Arkansas	Nebraska
California	Nevada
Colorado	New Hampshire
Florida	New Jersey
Illinois	New York
Kansas	North Carolina
Kentucky	Ohio

Oklahoma Pennsylvania Rhode Island Tennessee Texas Washington Wisconsin

Source: JMP Securities LLC

FIGURE 23. Revenue Mix in Veterinary Practice



Source: JMP Securities LLC

We asked our respondents a number of questions regarding the NSAID drugs they typically prescribe to treat cats and dogs with osteoarthritis. There is a consensus that **Metacam** is the most popular NSAID drug used to treat cats with osteoarthritis (41% of the time), while **Rimadyl** is the most popular NSAID drug used to treat dogs with osteoarthritis (49% of the time). For a single course of treatment, a cat diagnosed with osteoarthritis is typically prescribed pain medication for ~15 days, while a dog with osteoarthritis is prescribed pain medication for ~32 days on average. Total treatment days per year

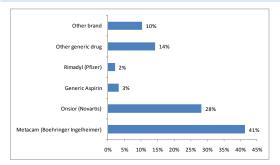


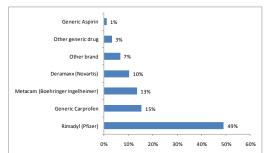
varies between cats and dogs diagnosed with osteoarthritis. A cat is typically prescribed pain medication for 75 days of total treatment per year on average and a dog is prescribed pain medication for a total of 214 treatment days per year. While vomiting, loss of appetite, and diarrhea are some of the common side effects that cats and dogs exhibit when on prescription drugs, we were somewhat "surprised" by a survey finding that our respondents indicated that nearly 50% of cats treated with NSAIDs and ~48% of dogs treated with NSAIDs exhibited **little or no side effects**.

In addition, we asked our respondents to comment on the impact of the drugs they prescribe on the medical condition of cats and dogs diagnosed with osteoarthritis. Nearly 70% of respondents said that the drugs had modestly improved the medical condition of the cats, while 26% of respondents have seen significant improvement in the medical condition of the cats. Conversely, there is a consensus that 84% of the respondents have seen significant improvement on the medical condition of dogs diagnosed with osteoarthritis, and 16% of the respondents indicated that the drugs had modestly improved the medical condition of dogs.

FIGURE 24. What percentage of the time do you prescribe the following drugs to treat CATS with osteoarthritis?

FIGURE 25. What percentage of the time do you prescribe the following drugs to treat DOGS with osteoarthritis?



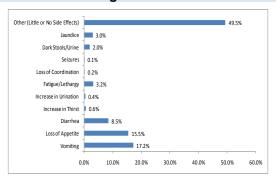


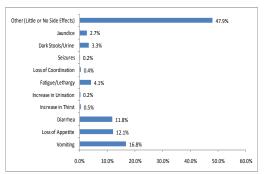
Source: JMP Securities LLC

Source: JMP Securities LLC

FIGURE 26. In what percentage of cases of cats treated with NSAIDS exhibit the following side effects?

FIGURE 27. In what percentage of cases of dogs treated with NSAIDS exhibit the following side effects?





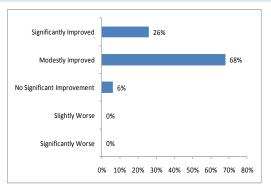
Source: JMP Securities LLC

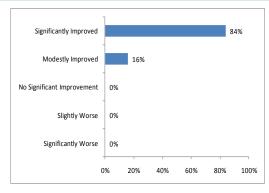
Source: JMP Securities LLC



FIGURE 28. What impact have the drugs you prescribe had on the medical condition of the cats diagnosed with osteoarthritis?

FIGURE 29. What impact have the drugs you prescribe had on the medical condition of the dogs diagnosed with osteoarthritis?



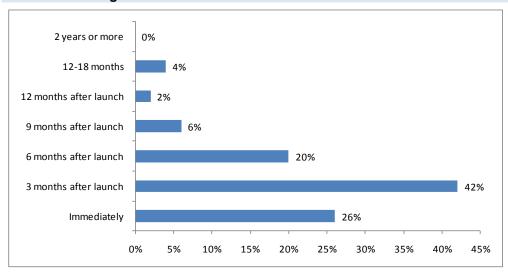


Source: JMP Securities LLC

Source: JMP Securities LLC

In an attempt to gauge the interest level for trying a new therapeutic, we asked our respondents how long after its initiation introduction into the market they would be willing to try, assuming that the new therapeutic is introduced to market and made available today. A majority of our respondents (42%) said that they would be willing to try three months after the product launch. Further, we asked our respondents to provide a percentage of the next 100 cats and dogs with various pain profiles that they would be willing to treat with this new therapeutic (drug) at various price points. Our respondents indicated that they would be willing to treat up to 63% of cats with post-operative pain, 61% of cats with acute pain (not post-operative), 58% of dogs with acute pain (not post-operative), and up to 54% of dogs with post-operative pain and up to 52% of dogs with osteoarthritis with this new drug if it were available today at \$0.75/day.

FIGURE 30. How long after an initial product launch would you be willing to try a new drug?



Source: JMP Securities LLC



FIGURE 31. If you had this drug available today, what percentage of the next 100 CATS with the following pain profiles would you be willing to treat with this drug, and how would this change depending on the price/day?

	\$0.75/day	\$0.85/day	\$0.90/day	\$1.00/day	\$1.10/day	\$1.15/day	\$1.25/day	\$1.30/day	\$1.50/day
Acute Pain/Trauma (not Post-operative)	61%	46%	43%	43%	37%	34%	32%	31%	28%
Post-Operative Pain	63%	46%	43%	44%	37%	35%	33%	32%	30%

Source: JMP Securities LLC

FIGURE 32. If you had this drug available today, what percentage of the next 100 DOGS with the following pain profiles would you be willing to treat with this drug, and how would this change depending on the price/day?

	\$0.75/day	\$0.85/day	\$0.90/day	\$1.00/day	\$1.10/day	\$1.15/day	\$1.25/day	\$1.30/day	\$1.50/day
Dogs with Osteoarthritis	52%	36%	33%	33%	26%	20%	20%	17%	15%
Acute Pain/Trauma (not Post-operative)	58%	43%	41%	41%	35%	33%	32%	30%	29%
Post-operative Pain	54%	41%	40%	41%	32%	28%	28%	26%	24%
Pain Management in Senior/Elderly Pets	53%	37%	33%	30%	23%	20%	20%	18%	17%

Source: JMP Securities LLC

We estimated the market opportunity for AT-001 in the longer term based on the above survey results (Figures 31 and 32). Note that we focus the market size for the indication of **osteoarthritis in dogs** for this exercise, and any other additional indications will provide upside to the total AT-001 market opportunity. We assume the percentages of the next 100 dogs at various price points in Figure 32 represent the market share percentages (%) at their corresponding price points. The chart below highlights the overall AT-001 market opportunity for the indication of osteoarthritis in dogs in 2025 at various price points and market share percentages.

FIGURE 33. AT-001 Market Opportunity for Dogs with Osteoarthritis



Source: JMP Securities LLC



\$40.0 70% \$32.3 61% \$35.0 60% \$30.3 \$29.6 \$28.7 \$30.0 \$28.2 \$28.4 \$27.6 \$27.6 \$27.3 50% 46% 43% 43% \$25.0 40% 37% 34% \$20.0 32% 31% 30% 289 \$15.0 20% \$10.0 10% \$5.0 0% \$0.0 \$0.75/day \$0.85/day \$0.90/day \$1.00/day \$1.10/day \$1.15/day \$1.25/day \$1.30/day \$1.50/day AT-001 US Annual Sales (\$ Million) Market Share (%)

FIGURE 34. AT-001 Market Opportunity for Cats with Osteoarthritis

Source: JMP Securities LLC

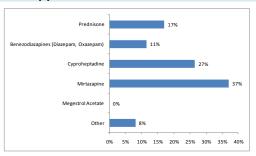
In addition to osteoarthritis and pain management, our respondents have experience in treating cats and dogs diagnosed with inappetance. Overall, they treat 167 cats and 230 dogs with inappetance per year. We asked our respondents a number of questions regarding the drugs they typically prescribe to stimulate appetite in cats and dogs. Mirtazapine and Cyproheptadine are the two most commonly used drugs to stimulate appetite in cats, while Mirtazapine and Prednisone are the two most popular drugs used to stimulate appetite in dogs. For a single course of treatment, both cats and dogs diagnosed with inappetance are typically prescribed medication for ~8 days, on average. The total treatment days per year slightly varies between cats and dogs diagnosed with inappetance. A cat is typically prescribed medication for 30.5 days of total treatment per year on average and a dog is prescribed medication for 31.2 treatment days per year.

We asked our respondents to comment on the impact of the drugs they prescribe on the medical condition of the cats and dogs diagnosed with inappetance. Seventy-percent of the respondents indicated that the drugs have modestly improved the medical condition of the cats, while 26% of the respondents have seen significant improvement on the medical condition of the cats. Likewise, 68% of the respondents said that the drugs has modestly improved the medical condition of the dogs, but 18% have seen no significant improvement, while 14% of the respondents have seen significant improvement on the medical condition of dogs with inappetance.

Moreover, we asked our respondents to provide a percentage of the next 100 cats and dogs with inappetance that they would be willing to treat with a new drug (currently under development) at various price points. Our respondents indicated that they would be willing to try the new drug in up to 69% of cats and up to 68% of dogs at the price of \$1.25/day. At \$2.00 per day, the penetration drops to 45% and 41%, respectively.

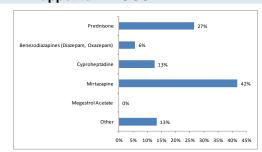


FIGURE 35. Drugs used to stimulate appetite in CATS



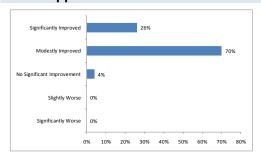
Source: JMP Securities LLC

FIGURE 36. Drugs used to stimulate appetite in DOGS



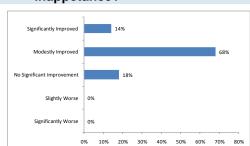
Source: JMP Securities LLC

FIGURE 37. What impact have the drugs you prescribe had on the medical condition of the cats diagnosed with inappetance?



Source: JMP Securities LLC

FIGURE 38. What impact have the drugs you prescribe had on the medical condition of the dogs diagnosed with inappetance?



Source: JMP Securities LLC

FIGURE 39. If a new drug currently under development uses a selective ghrelin agonist (hunger hormone) to stimulate appetite mechanism, in what PERCENTAGE of the next 100 DOGS and 100 CATS with inappetance would you be willing to try this new product. How would your answer change depending on the price/day?

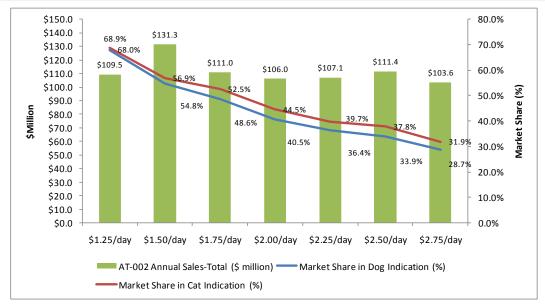
	\$1.25/day	\$1.50/day	\$1.75/day	\$2.00/day	\$2.25/day	\$2.50/day	\$2.75/day
Cats	69%	57%	53%	45%	40%	38%	32%
Dogs	68%	55%	49%	41%	36%	34%	29%

Source: JMP Securities LLC



We estimated the long-term market opportunity for AT-002 in the based on the above survey results Note that we focus the market size for the indication of **inappetance in both cats and dogs**. We assume the percentages of the next 100 dogs and cats at various price points in Figure 40 above represent the market share percentages (%) at corresponding price points. The chart below highlights the overall AT-002 market opportunity for the indication of inappetance in cats and dogs in 2025 at various price points and market share percentages.

FIGURE 40. AT-002 Market Opportunity for the Indication of Inappetance in Cats and Dogs



Source: JMP Securities LLC



# SIMILARITIES AND DIFFERENCES: PET THERAPEUTICS AND HUMAN THERAPEUTICS

The pet therapeutics business shares a number of characteristics with the business of developing and commercializing therapeutics for humans. These similarities include: (i) products that must be proven safe and effective in clinical trials to be approved by regulators, (ii) a reliance on new product development through research and development, and (iii) complex and regulated product manufacturing and products that are marketed based on labeled claims regarding impacts on health. However, we note that there are several key differences between the pet therapeutics and human therapeutics businesses, and we believe the following characteristics of pet therapeutics compare favorably with human therapeutics, including: (i) faster, less expensive and more predictable development, (ii) role and economics of veterinary practices, (iii) limited government and third-party payer exposure. We believe these factors should position the pet therapeutics industry for a sustainable growth profile, compared to the human therapeutics industry, which is often impacted by the patent expiration cycle.

## Faster, Less Expensive, and More Predictable Development

The development of pet therapeutics is generally faster and less expensive than for human therapeutics. For one, it requires fewer clinical studies, involves fewer subjects and is conducted directly in the target species. In addition, animals have shorter life spans than human beings, so studies can generate useful data more quickly. Furthermore, in the United States, the processes of the Food and Drug Administration's Center for Veterinary Medicine (CVM) differ from FDA processes for human drug development; the CVM encourages sponsors to contact the agency early in the development program and engage in an active dialogue with the CVM throughout the approval process. The ability to leverage both prior discoveries and results from pre-clinical and clinical testing of products from human biopharmaceutical companies, coupled with the interactive nature of the CVM review process, yields faster, less expensive, and more predictable development processes. This results in an enhanced process and greater capital and time efficiency of pet therapeutics relative to human drug development.

# **Economic Alignment Between Veterinarians and Therapeutics Companies**

Veterinary practices not only serve the primary goal of improving the health of pets, but often generate additional value and revenue growth by prescribing pet therapeutics. Unlike in the human pharmaceutical market, veterinarians often serve the dual role of doctor and pharmacist as pet owners typically purchase medicines directly from veterinarians. As such, the sale of pet therapeutics directly to pet owners can be a meaningful contributor to veterinary practice economics.

According to industry sources, approximately one-third of companion animal practice revenue comes from prescription drug sales, parasiticides, vaccines, and non-prescription medicines. According to DVM Newsmagazine's State of the Profession Report, in 2012, pharmaceutical sales, excluding vaccines and parasiticides, comprised only 9% of an average veterinarian practice's revenue. We believe that this revenue stream could be increased significantly with the introduction of novel therapeutics that have been specifically developed for pets.



# **Limited Government and Third-party Payer Exposure**

Pet healthcare products (including pet therapeutics) are typically cash pay businesses. Third-party insurance covers less than 5% of U.S. pet owners. Pet owners make decisions primarily on the advice of their veterinarian and not subject to government or third-party payer influence, which often plays a role in product and pricing decisions in human healthcare. We believe that this dynamic results in less pricing pressure than in human health.

# Lack of a Generics Infrastructure and Competition

Currently, generics have very limited exposure to the animal health/pet therapeutics market. The reasons for limited generics in the animal health space include the lack of a generic infrastructure to sell to veterinarians, the smaller size of each product opportunity, the importance of direct sales distribution and education to veterinarians, and the cash pay nature of the pet therapeutics business. We believe that this market dynamic results in less pricing pressure than in human therapeutics.

# FIGURE 41. Similarities and Differences Between Pet Therapeutics and Human Therapeutics

### Similarities

- Products must be proven safe for the intended use in the intended species.
- Products must have substantial evidence of effectiness for the intended use.
- Products must have a defined manufacturing process that ensures that the products can be made with high quality consistency.
- Product must be safe for human handling the product and for the environment.

#### **Key Differences**

## Pet Therapeutics

- · Shorter, less risky R&D cycles
- Veterinarian's Dual Role: Doctor and Pharmacist; Better Economics
- Cash pay; no third-party payers

# Human Therapeutics

- Longer, expensive R&D cycles
- Doctor and Pharmacist are separate roles
- Third-party payers influence decision-making (govt and insurance companies)
- Intense generic competition

Limited generic presence and competition

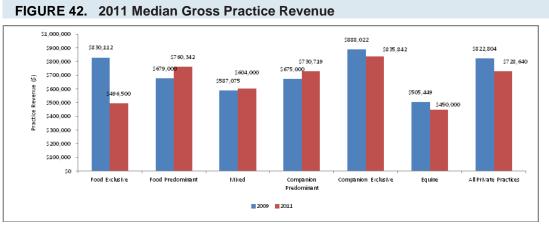
Source: Company reports, JMP Securities LLC



# AN OVERVIEW OF THE U.S. VETERINARY MARKET

Median gross practice revenue for all practices decreased from \$822,804 in 2009 to \$728,640 in 2011 (Figure 42). Change in median revenue varied by practice type between 2009 and 2011. Food animal exclusive, companion animal exclusive, and equine median revenue decreased during the 2009-2011 time frame, while food animal predominant, mixed animal, and companion animal predominant increased within the same period.

Gross revenue per veterinarian provides an indication of how revenue varies across practice types. From a definition standpoint, revenue per veterinarian is derived by dividing total practice revenue by the number of veterinarians (owners and associates) in the practice. In 2011, median gross practice revenue per veterinarian ranged from \$271,429 for equine practices to \$424,444 for companion animal exclusive practices.



Source: AVMA, JMP Securities LLC

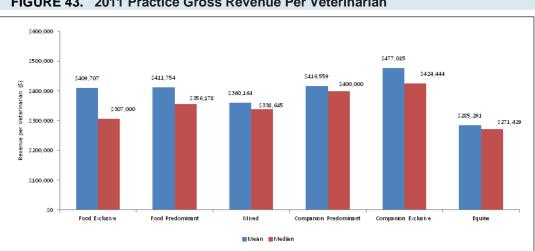


FIGURE 43. 2011 Practice Gross Revenue Per Veterinarian

Source: AVMA, JMP Securities LLC

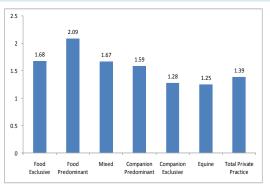


Median practice expense is compiled as the sum of all cash operating expenses, including non-owner (associate) veterinarian compensation. The median expense for all practices decreased from \$575,800 to \$528,000 between 2009 and 2011 (Figure 44).

FIGURE 44. 2011 Median Practice Expense

\$500,000 | \$526,318 | \$501,338 | \$528,000 |
\$500,000 | \$528,000 | \$540,000 | \$528,000 | \$540,000 | \$528,000 | \$540,000 | \$520,000 | \$520,000 | \$520,000 | \$520,000 | \$520,000 | \$520,000 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600 | \$600

FIGURE 45. Mean # of Owners Per Practice



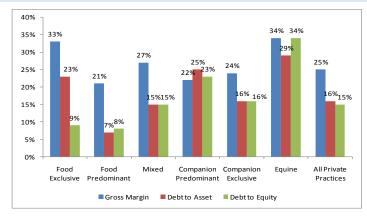
Source: JMP Securities LLC

Source: JMP Securities LLC

The mean number of owners per practice was 1.39 and the median 1.00 in 2011 (Figure 45). The mean number of owners ranged from 1.25 for equine practices to 2.09 for food animal predominant practices. All practice types had a median of one owner. Returns to practice owners were derived on a per-owner basis by dividing total net income by the number of full-time equivalent (FTE) owners in the practice. Median net income per owner was \$152,210 in 2011, compared to \$161,600 in 2009.

The median gross margin (defined as return to labor and management divided by practice gross revenue) for all practices was 25% in 2011, essentially flat compared to the 2009 level. As highlighted in Figure 46, gross margin varied from a low of 21% for food animal predominant practices to a high of 34% for equine practices in 2011. The debt to asset ratio (total practice debt ÷ total practice assets) is a measure of long-term financial solvency. The median ratio in 2011 was 16%, down from 27% in 2009. A second measure of long-term financial solvency is the debt to equity ratio (total practice debt ÷ equity). A ratio greater than 1.0 indicates that external financing of the practice exceeds the owner's capital contribution. Practices with high ratios may be undercapitalized. In 2011, the median debt to equity ratio for all private practices was 15%, compared to 25% in 2009. In 2011, the median debt to equity ratio ranged from 8% for food animal predominant practices to 34% for equine practices.

FIGURE 46. 2011 Median Financial Ratios



Source: AVMA, JMP Securities LLC



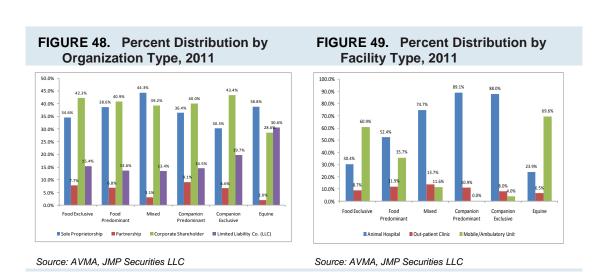
Figure 47 depicts the service categories as a percentage of practice revenue in 2011. Evaluating veterinary practice revenue according to service and product categories facilitates an understanding of the market for veterinary services and products. Owners indicated that prescription drug sales contributed the most to the overall revenue in five of the six practices.

30.0% 24.6% 25.0% 20.0% 15.7% 15.0% 12. 10.0% 5.0% Food Exclusive Food Mixed Companion Companion Equine Predominant Predominant Exclusive ■ Laboratory/Diagnostics ■ Radiology/Imaging ■ Prescription Drug Sales ■ Nonprescription Drug Sales ■ Food and Feed Sales

FIGURE 47. Selected Service Categories as a Percentage of Practice Revenue in 2011

Source: AVMA, JMP Securities LLC

In terms of type of organization, practices are classified as sole proprietorships, partnerships, corporate shareholders, limited liability partnerships, or franchises. The most prevalent form of practice organizations were corporate shareholders and sole proprietorship in 2011. With the exception of equine practices, these comprised >70% of veterinary practices.





Amongst various types of facilities used for veterinary practice, Mobile/Ambulatory units were the primary facility type of food animal exclusive (60.9%) and equine (69.6%) practices. Mixed animal (74.7%), companion animal exclusive (88.0%), and companion animal predominant (89.1%) practices primarily used animal hospital facilities (Figure 49).

All practice types were most concentrated in communities of 2,500 to 49,999 people, companion animal predominant (60.0%), mixed animal (52.6%), food animal exclusive (50.0%), companion animal exclusive (48.6%), equine (49.0%), and food animal predominant (48.8%) (Figure 50). In terms of geographic location of practice, food animal exclusive, food animal predominant, and mixed animal were most concentrated in Midwest, while companion exclusive and equine were concentrated in the South (Figure 51).

The majority of practice real estate was owned by veterinarians involved in the practice. The percentage of practices where a veterinarian in the practice owned the practice real estate ranged from 57.7% for food animal exclusive practices to 74.2% for mixed animal practices (Figure 52). In terms of the number of veterinarians, all practices were most concentrated in the "one veterinarian" category. Nonetheless, we note that the companion predominant practice was more "evenly" spread out among one veterinarian (34.5%), two veterinarians (29.1%), three veterinarians (14.5%), and four or more veterinarians (21.8%).

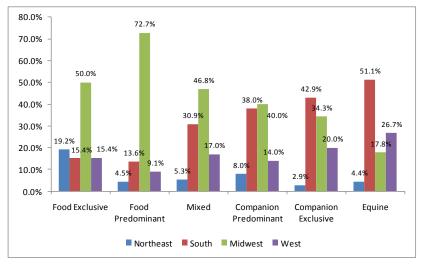
70.0% 60.0% 60.0% 52.6% 48.8% 48.6% 49 0% 50.0% 40.0% 37.1 36.5% 36.7% 30.8 30.0% 25.5 19 2% 20.0% 10.2% 8.2% 10.0% 7.0% 0.0% Food Exclusive Food Mixed Companion Companion Equine Predominant Predominant Exclusive Less than 2,500 2,500-49,999 50,000-499,999 ■ 500,000 or more

FIGURE 50. Percent Distribution by Community Size, 2011

Source: AVMA, JMP Securities LLC

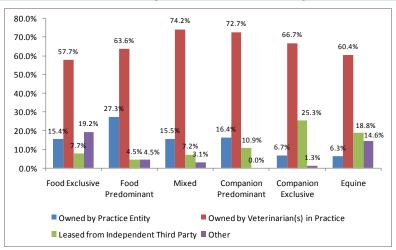


FIGURE 51. Percent Distribution by Geographic Location of Practice, 2011



Source: AVMA, JMP Securities LLC

FIGURE 52. Percent Distribution by Real Estate Ownership Status, 2011



Source: AVMA, JMP Securities LLC

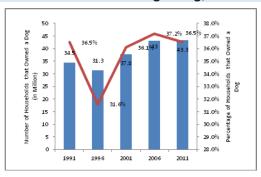


## THE U.S. PET MARKET

With a population of ~70 million in 2011, dogs remain one of America's favorite pets. In 2011, close to 43.3 million households owned a dog, but the percentage of households owning a dog decreased by 1.9% from 2006. At the end of 2011, there were about 74 million cats in the U.S., and over 30% of American households owned at least one cat, representing a decrease of 6.2% since 2006.

FIGURE 53. Percentage and Number of Households Owning a Dog, 1991-2011

FIGURE 54. Percentage and Number of Households Owning a Cat, 1991-2011



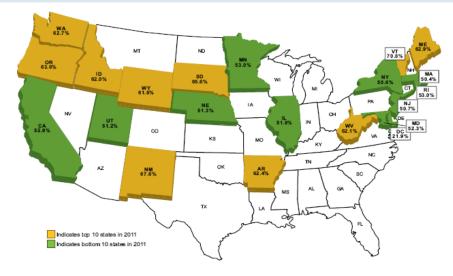


Source: AVMA, JMP Securities LLC

Source: AVMA, JMP Securities LLC

The percentage of households with one cat increased to almost 50% in 2011. In terms of regional difference, states with the greatest number of pet-owning households included California, Texas, and Florida. However, the highest percentage of pet owners in the U.S. is centered in the East South Central region, followed closely by the Mountain, West South Central, and West North Central regions (Figure 55).

FIGURE 55. Percentage of households that owned pets in 2011: Top and Bottom 10 States



Source: AVMA, JMP Securities LLC



Among all pets, dogs represented 64.4% of total veterinary visits in 2011, with care for dogs representing the highest percentage of all veterinary expenditures. On average, dogs visited the veterinarian 1.6 times in 2011, up almost 7% from 2006. Half of those households that didn't take their dog to the veterinarian at all in 2011, commented that it was because their dog wasn't sick or injured, and close to 30% said they couldn't afford it. Two-thirds of households believe routine check-ups are very important for their dog to live a long and healthy life. Households that consider their pet part of the family took their dog to the veterinarian most frequently in 2011. Veterinary visits decreased for households with two or more dogs.

While 75% of cat owners believe check-ups are somewhat/very important, the number of households taking their cat to the veterinarian just once a year has dropped 13.5% in the past five years. Slightly more than half of those households that didn't take their cat to the veterinarian at all in 2011 said it was because their cat wasn't sick or injured, and a fewer number said that they couldn't afford it.

Approximately 60% of the households indicated that a veterinary clinic was the first source they consulted with questions regarding the health of their dogs. One-quarter (25.7%) of the households indicated their first source was the Internet. On the other hand, approximately half of the households indicated that a veterinary clinic is the first source they consulted with on questions regarding the health of their cats. Three out-of-ten (29.8%) households indicated that their first source was the Internet.

FIGURE 56. First source consulted about the health of their dogs

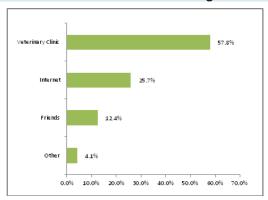
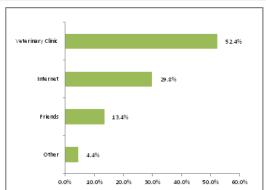


FIGURE 57. First source consulted about the health of their cats



Source: AVMA, JMP Securities LLC

Source: AVMA, JMP Securities LLC



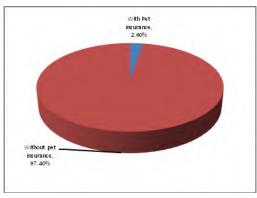
Among dog-owning households, 5.7% indicated that they had pet insurance for their dogs in 2011. Among cat-owning households, 2.6% indicated that they had pet insurance for their cats in 2011.

FIGURE 58. Insurance coverage in dogowning households

Without pet insurance, 94,30%

Source: AVMA, JMP Securities LLC

FIGURE 59. Insurance coverage in catowning households



Source: AVMA, JMP Securities LLC



The animal health industry is projected to grow at a 6.0% CAGR from \$~22 billion in 2011 to ~\$29 billion bv 2016.

## AN OVERVIEW OF PET THERAPEUTICS MARKET

The worldwide animal health business is divided into livestock (cattle, poultry, sheep) and companion animals (cats, dogs, horses). As people regularly consume protein and dairy products, assuring livestock or food animal health for human consumption is important, as demand remains strong around the globe with growing populations and growth in emerging markets. Likewise, companion animals associated with emotional attachments to owners require products to stay in good health just as human beings do.

According to a survey conducted by the American Veterinary Medical Association, 63.2% of pet owners consider their pets as family members. According to Vetonosis, a research and consulting firm specializing in global animal health and veterinary medicine, total industry sales for animal health (including both livestock and companion animals) in 2011 was ~\$22 billion, and is projected to grow at a 6.0% CAGR to ~\$29 billion by 2016, primarily driven by both pricing and volume growth, in our view.

In addition, the companion animal business will likely see the most significant growth from emerging countries, including Asia Pacific and Latin America regions, as solid GDP growth and increased discretionary spending power likely leads to wider pet adoption in the regions. On the other hand, as the global economic recovery continues its momentum and disposable income increases, expenditures per pet will likely increase as well.

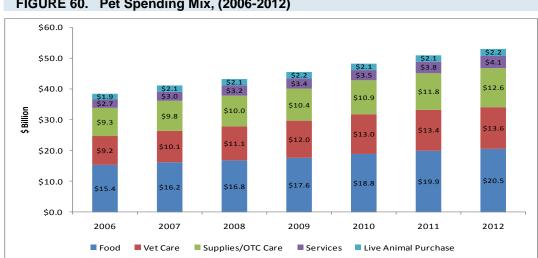


FIGURE 60. Pet Spending Mix, (2006-2012)

Source: APPA, JMP Securities LLC

# The Market for Pet Therapeutics

According to a survey conducted by the American Pet Products Association (APPA), U.S. consumers spent an estimated \$53 billion on companion pets in 2012, up ~87% over 2001, representing a CAGR of ~5.9% (Figure 2). There are ~96 million cats and 83 million dogs in the U.S. and 85 million cats and 74 million dogs in Europe. According to APPA, the U.S. is the single largest pet market, and currently 68% of U.S. households have a pet. The pet market has consistently grown in the mid-single digits, exceeding inflation, despite global economic cycles at various points in time. We expect the growth trend to continue with an annual industry growth rate of ~3-5% over the next three years.

July 22, 2013 43



FIGURE 61. Total U.S. Pet Industry Expenditures (in billions)



Source: American Pet Products Association (APPA), JMP Securities LLC

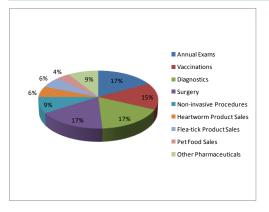
The veterinary care segment has been among the fastest growing segments of the overall \$53 billion U.S. pet market. The U.S. veterinary care segment (including pet and animal health markets) has increased from \$9.2 billion in 2006 to \$13.6 billion in 2012, representing a CAGR of 6.7% (Figure 62). Figures 63 depicts an average veterinary revenue mix in 2012. According to APPA, of this \$13.6 billion, ~\$6.3 billion is related to consumer spending in pet medicines, which included ~\$4.7 billion for parasiticides and vaccines, and approximately \$1.6 billion for pet therapeutics. In the short-to-medium term, we expect the pet market to continue to grow, driven, in part, by the expansion of the veterinary care segment. More importantly, we believe that the introduction of novel pet therapeutics offering significant safety and efficacy benefits over existing products could result in pet therapeutics achieving a larger share of total consumer spending on pets.

FIGURE 62. U.S. Veterinarian Care Spending (in Billions)



Source: American Pet Products Association (APPA)

FIGURE 63. Average Veterinary Practice
Revenue Mix 2012



Source: DVM Newsmagazine's State of the Profession Report



## AN OVERVIEW OF THE REGULATORY PROCESS FOR PET THERAPEUTICS

As discussed previously, animals are divided into two categories: companion animals (or pets), such as cat and dogs, and food animals for human consumption, such as poultry and cattle.

## **U.S. Regulatory Approval**

Animal pharmaceuticals, biologics, and pesticides are regulated by the U.S. government. Animal health products for food and companion animals are vigorously researched and tested for safety, purity, and efficacy by the developers before being submitted for additional review, research, testing, and ultimately, approval by government regulatory agencies. The agencies involved in the approval and regulatory process of the animal products include the FDA's Center for Veterinary Medicine (CVM), EPA, and USDA depending on the classification of the products.

Navigating the regulatory pathways for new products takes an average of 5-7 years and the research and development process requires the investment of millions of dollars. The results are products that the animal health industry and the American public can count on to be pure, safe, potent, and effective. Figure 4 highlights the shorter project lifecycle from product development to approval in animal/pet therapeutics relative to that of human therapeutics.

- O Pharmaceuticals Food and Drug Administration (FDA)/Center for Veterinary Medicine (CVM): The CVM at the FDA regulates animal pharmaceuticals under the Food, Drug, and Cosmetics Act. The agency tests, approves, licenses, and regulates all pharmaceutical products. When a new drug has been determined to be a potentially useful medicine, the pharmaceutical company begins working closely with the FDA to review development plans and to set up testing protocols. Reviews of studies and testing continues throughout the process, which can take 7-10 years before an approval is granted.
- Vaccines and Biologics USDA Center for Veterinary Biologics (CVB): The USDA Center for Veterinary Biologics regulates veterinary vaccines and some biologics pursuant to the Virus, Serum, Toxin Act. The agency evaluates the purity, safety, potency, and effectiveness of all vaccines and biological products prior to licensing. The review process, which includes challenge studies, safety trials, and manufacturing testing, can take three to five years.
- Pesticides Environmental Protection Agency (EPA): The EPA regulates veterinary pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act. Most topical products used for treatment of flea and tick infestations are regulated by the EPA. The agency evaluates the safety and effectiveness of pesticides, and develops safety guidelines to closely oversee their use. Manufacturers must provide scientific evidence demonstrating with reasonable certainty that a product will cause no harm to humans, the environment, or non-target species. The process from discovery through long-term toxicology studies and EPA review takes 5-7 years on average. It should be noted, however, that the mechanism of action of a drug can impact whether the EP or CVB evaluates it. For example, a pesticide that acts systemically will be evaluated by the CVB, not the EPA.



In Aratana's case, all of its current product candidates are animal pharmaceuticals regulated by the CVM. Manufacturers of animal health pharmaceuticals, including Aratana, must show their products to be safe, effective, and produced by a consistent method of manufacture. The CVM's basis for approving a drug application is documented in a Freedom of Information Summary. Aratana will be required to conduct post-approval monitoring of products and to submit reports of product quality defects, adverse events, or unexpected results to the CVM's Surveillance and Compliance group.

> YR10 YR3 YR4 YR6 YR8 YR11 Proof of Co cept in Lab Animals SAR Chemi on of Lead Animal Toxicology Н Animal U **Human Clinical Studies** pK In vitro IND Filing M Chemistry Optimizatio Phase I Α Field Trials Phase II N Final Formulation Phase III Selection of Lead Proof of Concept in Dogs/Cats pK in Dogs/Cats Ν API and Formulation Development ose election M robe Safety in Dogs/Cats Ęυ inal Formulation

FIGURE 64. Shorter Product/Drug Lifecycle for Animal Health Products

## Requirements for Approval of Veterinary Pharmaceuticals for Pets

As a condition to regulatory approval for the sale of animal products, regulatory agencies worldwide require that a product to be used for pets be demonstrated to:

be safe for the intended use in the intended species;

Source: Company reports

- have substantial evidence of effectiveness for the intended use:
- have a defined manufacturing process that ensures that the product can be made with high quality consistency; and
- O be safe for humans handling the product and for the environment.



## Safety

To determine that a new veterinary drug is safe for use, regulatory bodies will require developers/manufacturers to provide data from a safety study generated in laboratory cats and dogs tested at doses higher than the intended label dose, over a period of time determined by the intended length of dosing of the product.

In the case of the CVM, the design and review of the safety study and the study protocol are completed prior to initiation of the study to help ensure that the data generated will meet FDA requirements. These studies are conducted under rigorous quality control, including good laboratory practice (GLP), to ensure integrity of the data. They are designed to clearly define a safety margin, identify any potential safety concerns, and establish a safe dose for the product. This dose and effectiveness is then evaluated in the pivotal field effectiveness study, where the product is studied in the animal patient population in which the product is intended to be used. Field safety data, obtained in a variety of breeds and animals kept under various conditions, are evaluated to ensure that the product will be safe in the target population.

Safety studies are governed by regulations and regulatory pronouncements that provide the parameters of required safety studies and are utilized by regulatory bodies in the United States, the European Union, and Japan.

#### **Effectiveness**

Early pilot studies may be done in laboratory cats or dogs to establish effectiveness and the dose range for each product. Data on how well the drug is absorbed when dosed by different routes and the relationship of the dose to the effectiveness are studied. When an effective dose is established, a study protocol to test the product in real world conditions is developed prior to beginning the study. In the case of the CVM, the pivotal effectiveness field study protocol is submitted for review and concurrence prior to study initiation, to ensure that the data generated will meet requirements.

The pivotal field effectiveness study must be conducted with the formulation of the product that is intended to be commercialized, and is a multi-site, randomized, controlled study, generally with a placebo control. To reduce bias in the study, individuals doing the assessment are not told whether the subject is in the group receiving the treatment being tested or the placebo group. In both the United States and the European Union, the number of patients enrolled in the pivotal field studies is required to be approximately 100 to 150 animal subjects treated with the test product and a comparable number of subjects in the control group that receive the placebo. In many cases, a pivotal field study may be designed with clinical sites in both the European Union and the United States, and this single study may satisfy regulatory requirements in both the European Union and the United States.

## Chemistry, Manufacturing, and Controls, or CMC

To ensure that the product can be manufactured consistently, regulatory agencies will require developers/manufacturers to provide documentation of the process by which the API is made and the controls applicable to that process that ensure the API and the formulation of the final commercial product meet certain criteria, including purity and stability. After a product is approved, developers will be required to communicate with the regulatory bodies any changes in the procedures or manufacturing site. Both API and commercial formulations are required to be manufactured at facilities that practice cGMP.



### **Environmental and Human Safety**

In the case of Aratana, it will not be required under United States law to provide an environmental impact statement for products currently in development if the products are given at the home of the pet's owner or in a veterinary hospital. If products might result in some type of environmental exposure or release, the environmental impact must be assessed. For approval in the EU, a risk assessment for potential human exposure will be required.

#### Labeling, All Other Information, and Freedom of Information Summary

Developers will be required to submit the intended label for the product, and also any information regarding additional research that has been conducted with the drug, to the CVM and other regulatory bodies for review. Developers will draft, and submit for regulatory review, the Freedom of Information Summary for use in the United States. This summary outlines the studies and provides substantial information the CVM uses to assess the drug's safety and effectiveness and publishes on its website.

## Regulatory Process at the FDA

To begin the development process for products in the United States, developers establish an Investigational New Animal Drug (INAD) file with the CVM. The developers will then hold a predevelopment meeting with the CVM to reach a general agreement on the plans for providing the data necessary to fulfill requirements for a NADA. During development, they will submit pivotal protocols to the CVM for review and concurrence prior to conducting the required studies. Developers will gather and submit data on manufacturing, safety, and effectiveness to the CVM for review, and this review will be conducted according to timelines specified in the Animal Drug User Fee Act. Once all data have been submitted and reviewed for each technical section – safety, effectiveness, and CMC – the CVM will issue a technical section complete letter as each section review is completed, and when the three letters have been issued, the company will compile a draft of the Freedom of Information Summary, the proposed labeling, and all other relevant information, and submit these as an administrative NADA for CVM review. Generally, if there are no deficiencies in the submission, the NADA will be issued within four to six months after submission of the administrative NADA. After approval, the developers will be required to collect reports of adverse events and submit them on a regular basis to the CVM.

## **International Regulatory Approval**

In Europe, the European Medicines Agency (EMA) regulates the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union. Its veterinary review section is distinct from the review section that reviews human drugs. The Committee for Veterinary Medicinal Products is responsible for scientific review of the submissions for animal pharmaceuticals and vaccines but the EMA makes the final decision on the approval of products. Once a centralized marketing authorization is granted by the EMA, it is valid in all European Union and European Economic Area-European Free Trade Association states. In general, the requirements for regulatory approval of an animal health product in the European Union are similar to those in the United States, requiring demonstrated evidence of purity, safety, efficacy, and consistency of manufacturing processes.



For the rest of world (ROW), each other country has its own regulatory requirements for approving and marketing veterinary pharmaceuticals. In Brazil, the Ministry of Agriculture, Livestock Products and Supply, or MAPA, is responsible for the regulation and control of pharmaceuticals, biologicals, and feed additives for animal use. MAPA's regulatory activities are conducted through the Secretary of Agricultural Defense and its Livestock Products Inspection Department. In addition, regulatory activities are conducted at a local level through the Federal Agriculture Superintendence. These activities include the inspection and licensing of both manufacturing and commercial establishments for veterinary products, as well as the submission, review, and approval of pharmaceuticals, biological, and feed additives.

In Australia, the Australian Pesticides and Veterinary Medicines Authority, or APVMA, is the Australian government statutory authority for the registration of all agricultural and veterinary products. The APVMA assesses applications from manufacturers of veterinary pharmaceuticals and related products. Many country specific regulatory laws contain provisions that include requirements for labeling, safety, efficacy, and manufacturers' quality control procedures to ensure the consistency of the products, as well as company records and reports. With the exception of the European Union, the regulatory agencies of most other countries generally refer to the FDA, USDA, EMA, and other international animal health entities, including the World Organisation for Animal Health and the Codex Alimentarius Commission, in establishing standards and regulations for veterinary pharmaceuticals and vaccines.

There have been relatively few approvals granted by the CVM and the European Medicines Agency (EMA) in recent years despite a generally faster, less expensive and more predictable regulatory approval process for pet therapeutics than human therapeutics. For example, in 2012, 39 new human drugs were approved by the FDA, while only 11 new drugs were approved by the CVM, six of which were for use in cats or dogs. In 2011, the FDA approved 35 human drugs while only 12 new drugs were approved by the CVM. In Europe, the EMA approved 52 applications for human drugs in 2012, compared to three veterinary drugs.



## LICENSING AGREEMENTS

#### **Exclusive License Agreements with RaQualia**

In December 2010, Aratana entered into two agreements with RaQualia under which Aratana exclusively licensed intellectual property rights relating to AT-001 and AT-002 in the animal health space. In connection with these agreements, Aratana obtained the rights to 14 granted U.S. patents, as well as foreign counterparts and other patent applications. Under these agreements, Aratana received exclusive, worldwide licenses to develop, manufacture, and commercialize AT-001 and AT-002 in the animal health space, except that the company cannot develop, manufacture, or commercialize injectable AT-001 products in Japan, Korea, China, or Taiwan. Additionally, Aratana has the right to grant sub-licenses to third parties under these agreements. The company is responsible for using commercially reasonable efforts to develop and commercialize AT-001 and AT-002. The patents licensed under this agreement terminate between 2012 and 2029.

Aratana paid RaQualia upfront license fees under each of the AT-001 and AT-002 agreements, and is responsible for contingent milestone payments upon achievement of development and regulatory milestones and royalties on net sales of licensed products. Additionally, Aratana is required to pay to RaQualia a certain portion of royalties received from any sub-licensees. The royalty obligations apply on a country-by-country and licensed product-by-licensed product basis, and end upon the expiration or abandonment of all patents with valid claims covering a licensed product in a given country.

Each of the AT-001 and AT-002 agreements continues until terminated. RaQualia may terminate the AT-001 agreement or the AT-002 agreement if Aratana fails to pay any undisputed fee under the relevant agreement and do not cure such failure within 60 days after the notification of such failure. In addition, Aratana may terminate the AT-001 agreement or the AT-002 agreement, or any license granted under either agreement, on a patent-by-patent and country-by-country basis at will, upon 30 days' prior written notice to RaQualia.

#### **Exclusive License Agreement with Pacira**

In December 2012, Aratana entered into an exclusive license agreement and related exclusive supply agreement with Pacira Pharmaceuticals, Inc. Under the license agreement, Aratana received an exclusive, worldwide license to develop and commercialize, but not to manufacture, AT-003 in the veterinary field. Aratana was not granted the right to enforce patents licensed with respect to AT-003 against any third-party infringement, although it has certain limited rights to request that Pacira enforce such patents against infringement. In connection with this agreement, Aratana obtained the rights to eight granted U.S. patents and five pending U.S. patent applications, as well as foreign counterparts and other patent applications. Aratana has the right to grant sub-licenses to third parties outside the U.S. upon Pacira's approval. Aratana is responsible for using commercially reasonable efforts to develop and commercialize AT-003, and for launching AT-003 within a specified time period following regulatory approval in certain countries.

Aratana paid Pacira an upfront fee and are responsible for contingent milestone payments upon the achievement of certain development and commercial milestones, of up to \$42.5 million in aggregate. In addition, Aratana must pay Pacira a royalty on net sales of AT-003 by the company and its affiliates. Aratana must also pay to Pacira a percentage of all payments received from any sub-licensee. After a certain number of years of sales of AT-003, Aratana is responsible for meeting minimum annual revenue requirements. If Aratana fails to meet these requirements, either Aratana or Pacira may terminate the license agreement. The term of the license agreement extends for 15 years, until December 5, 2027, after which Aratana has the option to renew the term for an additional five years.



#### MANAGEMENT TEAM

#### Steven St. Peter, M.D., Director, President and Chief Executive Officer

Dr. St. Peter is one of the company's founders and has served as President and Chief Executive Officer since September 2012. He has been a member of the company's board of directors since December 2010 and served as the chairman of the board of directors from December 2010 to September 2012. Dr. St. Peter was a managing director of MPM Asset Management LLC from January 2004 to May 2012, where he focused his investments on both venture and buyout transactions across the pharmaceuticals and medical technology industries. He has previous investment experience from Apax Partners and The Carlyle Group, two private equity firms. Dr. St. Peter was previously an assistant clinical professor of medicine at Columbia University. He received his M.D. from Washington University and completed his residency and fellowship at the Hospital of the University of Pennsylvania. Prior to his medical training, he was an investment banker at Merrill Lynch. Dr. St. Peter also holds an M.B.A. from the Wharton School of Business at the University of Pennsylvania and a B.A. in Chemistry from the University of Kansas.

#### Ernst Heinen, D.V.M., Ph.D., Head of Drug Evaluation and Development

Dr. Heinen has served as Head of Drug Evaluation and Development since June 2012. From 1990 to 2012, Dr. Heinen held positions of increasing responsibility at Bayer Animal Health, the animal health division of Bayer AG, where he ultimately served as Vice President of Research & Development and Veterinary Technical Services, Pets. Dr. Heinen previously served on the boards of the Kansas City Area Development Council and the Center for Animal Health Innovation, and he is the author of dozens of scientific articles and presentations focused on the animal health industry. Dr. Heinen received a veterinary degree and a D.V.M. in veterinary microbiology from the Justus-Liebig-University of Giessen Veterinary School in Giessen, Germany and is a certified specialist in veterinary microbiology.

## Louise A. Mawhinney, Chief Financial Officer

Ms. Mawhinney has served as Chief Financial Officer since September 2012. From May 2008 to September 2012, Ms. Mawhinney served as Chief Financial Officer of Ikonisys Inc., a medical device and diagnostic company. From September 2006 to March 2008, she served as Senior Vice President and Chief Financial Officer at Helicos BioSciences Corporation, a genetic analysis technology company. Prior to her tenure at Helicos, Ms. Mawhinney was Chief Financial Officer for ArQule, Inc., a publicly-traded biotechnology company. She also formerly worked in the tax department of KPMG LLP in Boston. Additionally, Ms. Mawhinney serves as a board member and treasurer for Class, Inc., a non-profit organization. Ms. Mawhinney holds a Master's degree from the University of St. Andrews. She has been a Certified Public Accountant active in Massachusetts since 1989.

## Linda Rhodes, V.M.D., Ph.D., Director and Chief Scientific Officer

Dr. Rhodes has served as Chief Scientific Officer since September 2012 and as a member of our board of directors since February 2011. In addition, she served as the company's Chief Executive Officer from February 2011 to September 2012. In 2001, Dr. Rhodes was a founding partner of AlcheraBio LLC, an animal health consulting and contract research firm, which was acquired in October 2008 by Argenta, a New Zealand animal health formulations and contract manufacturing organization, and she served as



its Vice President of Clinical Development from February 2008 to February 2011. She is an adjunct professor for the Graduate School of Animal Science at Rutgers University and is a member of the board of directors of the Alliance for Contraception in Cats and Dogs, a non-profit organization. She has been a member of the board of directors of ImmuCell Corporation since 2000 and a member of its audit and compensation committees since August 2005 and is the chairman of its compensation committee.

From 1998 to 2001, she was a director of production animal development projects and new technology assessment at Merial Ltd. Prior to that role, she held various research positions at Merck Research Laboratories and Sterling Winthrop Drug Company. She has held several teaching positions and worked as a bovine veterinarian in private practice. She earned her Ph.D. in Physiology/Immunology from Cornell University and her V.M.D. from the University of Pennsylvania School of Veterinary Medicine, graduating summa cum laude. She also holds a Bachelor of Arts degree from Sarah Lawrence College. Dr. Rhodes was selected to serve on Aratana's board because of her background as an accomplished entrepreneur, executive, and scientist in the pet therapeutics industry.

## Julia A. Stephanus, Chief Commercial Officer

Ms. Stephanus has served as Chief Commercial Officer since January 2013. From September 2010 through December 2012, Ms. Stephanus was director of the global pet franchise for Ceva Animal Health, where she oversaw the commercial development of new products, as well as global marketing for strategic pet products. In 2006, Ms. Stephanus founded Summit VetPharm, the developer of Vectra, a pet parasiticide product line, and served as its President and Chief Executive Officer until it was acquired by Ceva Animal Health in August 2010.

Prior to founding Summit VetPharm, Ms. Stephanus worked in various sales and marketing positions for Pfizer Inc. and its legacy companies, where she had the commercial responsibility for, among other things, the development and global launch of two highly profitable pet products: Rimadyl, the first NSAID approved for osteoarthritis in dogs, and Revolution, the first topical endectocide for heartworm and fleas in cats and dogs. Ms. Stephanus received a B.A. from Indiana University and has attended executive education programs at Harvard, Columbia and the Wharton School of Business at the University of Pennsylvania.

Source: Company website



#### FINANCIAL OVERVIEW

#### Revenue

Aratana currently does not have any products approved for sale, and thus have not generated any revenues since the company's inception, and management does not expect to generate any revenue from the sale of products in the near term. If the development efforts result in clinical success and regulatory approval or collaboration agreements with third parties for any of the product candidates, the company may generate revenues from those product candidates.

#### **Operating Expenses**

Aratana's operating expenses to date, have been largely attributable to research and development (R&D) activities related to AT-001 and AT-002. The company incurred \$7.3 million in R&D expense in 2012. R&D expense consists of costs associated with the company's product development efforts (including target animal studies), as well as wages, stock-based compensation, and employee benefits for all employees engaged in scientific research and development functions, and other operational costs related to the research and development activities (including facility-related expenses, external costs of outside contractors engaged to conduct target animal studies, contract manufacturers and API chemistry service providers, license payments made under the company's licensing agreements, regulatory, professional and consulting fees, travel costs, and allocated corporate costs).

In addition, the company incurred \$3.0 million and \$1.5 million, respectively, in general and administrative expense and in-process research and development expense in 2012. General and administrative expense consists primarily of personnel costs, including salaries, related benefits and stock-based compensation for employees in administration, finance and business development, while in-process research and development expense is comprised of costs associated with acquired in-licensed technology(including upfront and milestone payments).

## **Income Taxes**

As of December 31, 2012, Aratana had federal and state net operating loss carry-forwards of \$1.1 million and \$1.0 million, respectively, and federal and state research and development tax credit carry-forwards of \$42,000 and \$56,000, respectively. The company has not recorded any U.S. Federal or state income tax benefits for the losses or research and development tax credits, as they have been offset in full by valuation allowances.

#### **Debt Financing**

Subsequent to December 31, 2012, Aratana received additional funding of \$2.8 million from the sale of its series C convertible preferred stock in January and February 2013 and \$5.0 million from borrowings under the company's loan and security agreement with Square 1 Bank in March 2013.

#### **Initial Public Offering**

On June 27, 2013, Aratana completed an initial public offering, issuing 5.8 million shares of common stock at a price of \$6.00/share, resulting in net proceeds of \$35 million. The company plans to use the net proceeds of the offering to: (i) in-license and develop additional product candidates, (ii) commercialize its current and future product candidates, (iii) establishing a direct sales organization in



the U.S., and (iv) for general corporate and working capital purposes. Cash on hand should be enough to fund the clinical efforts for AT-001, AT-002, and AT-003 to completion. However, the company will likely need to raise additional capital in order to successfully commercialize these products and expand its product pipeline.

# FIGURE 65. Aratana Therapeutics - Income Statement

Aratana Therapeutics, Inc.													
P&L													
(\$'s in 000's)													
	2013	<u>2014</u>	2015	2016	2017	2018	<u>2019</u>	2020	2021	2022	2023	2024	2025
AT-001 Indication A&B	\$0	\$0	\$0	\$10,235	\$26,326	\$44,636	\$66,644	\$95,420	\$115,842	\$127,582	\$135,198	\$143,304	\$151,929
AT-001 Cat OA	0	0	0	0	0	0	0	0	0	0	0	0	0
AT-002 Indication A&B	0	0	0	11,617	25,627	40,510	54,194	67,871	83,155	93,367	106,267	116,467	121,899
AT-002 Indication C	0	0	0	0	0	0	0	0	0	0	0	0	0
AT-003	0	0	0	5,132	15,481	19,893	24,355	28,869	34,629	40,556	45,739	51,067	56,545
AT-004	0	0	0	0	22,253	34,663	47,914	63,413	77,097	86,297	94,777	102,577	109,023
AT Other Products	0	0	0	0	0	0	0	0	0	0	0	0	0
Projected Wholesale Revenue	\$0	\$0	\$0	\$26,983	\$89,687	\$139,702	\$193,107	\$255,573	\$310,723	\$347,802	\$381,980	\$413,415	\$439,396
Distributor Margin & ISO	0	0	0	5,962	19,842	30,975	42,866	56,786	69,048	77,259	84,832	91,788	97,520
Gross Revenue	\$0	\$0	\$0	\$21,021	\$69,845	\$108,727	\$150,241	\$198,786	\$241,675	\$270,543	\$297,149	\$321,627	\$341,876
Total Discounts and Rebates	0	0	0	2,225	4,350	5,713	6,126	6,211	6,269	6,328	6,386	6,444	6,502
Net Revenue	\$0	\$0	\$0	\$18,796	\$65,495	\$103,014	\$144,115	\$192,575	\$235,406	\$264,216	\$290,763	\$315,183	\$335,374
Total Royalties & Adjustments	1,000	5,500	3,500	2,095	7,056	10,578	14,394	18,807	22,918	25,927	28,667	31,253	33,519
Net Revenue after Royalties	(\$1,000)	(\$5,500)	(\$3,500)	\$16,701	\$58,439	\$92,435	\$129,720	\$173,768	\$212,488	\$238,289	\$262,096	\$283,930	\$301,855
Total COGs	0	0	0	3,347	11,133	17,363	24,017	31,802	38,667	43,272	47,519	51,422	54,642
Gross Profit (US)	(\$1,000)	(\$5,500)	(\$3,500)	\$13,354	\$47,305	\$75,072	\$105,704	\$141,965	\$173,820	\$195,016	\$214,577	\$232,508	\$247,213
Milestones & Royalties (OUS)	908	7,900	10,684	9,254	5,830	9,081	12,552	16,612	20,197	22,607	24,829	26,872	28,561
Total Gross Profit	(\$92)	\$2,400	\$7,184	\$22,608	\$53,135	\$84,153	\$118,256	\$158,578	\$194,017	\$217,623	\$239,406	\$259,380	\$275,774
Sales Force	0	0	1,034	5,800	8,825	14,465	20,105	20,608	21,123	21,651	22,192	22,747	23,316
Advertising and Promotion	0	0	2,400	13,630	17,653	18,934	18,888	16,787	16,905	17,022	17,140	17,258	15,615
Marketing & Other	1,254	1,317	1,913	2,066	2,518	3,358	3,958	4,057	4,159	4,263	4,369	4,479	4,591
Total Sales & Marketing	\$1,254	\$1,317	\$5,347	\$21,495	\$28,996	\$36,757	\$42,952	\$41,452	\$42,186	\$42,936	\$43,701	\$44,483	\$43,521
Profit after S&M	(\$1,346)	\$1,083	\$1,838	\$1,113	\$24,139	\$47,396	\$75,304	\$117,126	\$151,831	\$174,687	\$195,705	\$214,897	\$232,252
Research & Development	7,579	12,980	12,716	7,470	8,637	9,575	10,603	11,814	12,885	13,605	14,269	14,880	15,384
General & Administrative	2,446	2,568	2,696	2,750	3,438	4,636	6,485	8,666	10,593	11,890	13,084	14,183	15,092
EBITDA	(\$11,371)	(\$14,465)	(\$13,575)	(\$9,107)	\$12,064	\$33,185	\$58,216	\$96,645	\$128,353	\$149,192	\$168,351	\$185,834	\$201,776
EBITDA (US Only)	(\$12,279)	(\$22,365)	(\$24,259)	(\$18,361)	\$6,234	\$24,104	\$45,664	\$80,033	\$108,156	\$126,585	\$143,523	\$158,962	\$173,215
EBITDA Margin of Wholesale Revenue				-33.8%	13.5%	23.8%	30.1%	37.8%	41.3%	42.9%	44.1%	45.0%	45.9%
Income Tax 35%	\$0	\$0	\$0	\$0	\$0	\$0	-\$19,232	-\$33,826	-\$44,924	-\$52,217	-\$58,923	-\$65,042	-\$70,622
Net Income	(\$11,371)	(\$14,465)	(\$13,575)	(\$9,107)	\$12,064	\$33,185	\$38,984	\$62,820	\$83,429	\$96,975	\$109,428	\$120,792	\$131,154
Net Margin (%)	(***,****)	(***,****)	(4:2,2:2)	-48.5%	18.4%	32.2%	27.1%	32.6%	35.4%	36.7%	37.6%	38.3%	39.1%
Diluted Share Count (000s)	19,860	20,000	21,000	22,000	23,000	24,000	25,000	26,000	27,000	28,000	29,000	30,000	31,000
Diluted EPS	(\$0.57)	(\$0.72)	(\$0.65)	(\$0.41)	\$0.52	\$1.38	\$1.56	\$2.42	\$3.09	\$3.46	\$3.77	\$4.03	\$4.23

Source: Company reports, JMP Securities LLC



# FIGURE 66. Aratana Therapeutics - Balance Sheet

Aratana Therapeutics, Inc.															
Balance Sheet															
(\$'s in 000's)															
	2011	2012	1Q'13	2Q'13E	3Q'13E	4Q'13E	2013E	1Q'14E	2Q'14E	3Q'14E	4Q'14E	2014E	2015E	2016E	2017E
Assets															
Current Assets															
Cash and cash equivalents	6,002	13,973	19,270	25,384	25,433	16,542	16,542	16,884	12,270	8,166	12,330	12,330	7,202	1,604	15,191
S-t marketable securities	6,382	6,382	6,382	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000
Accounts Receivable	-	650	-	-	-	-	-	-	-	-	-	-	-	2,177	6,169
Inventory	-	-	-	-	-	-	-	-	-	-	-	-	-	1,087	2,753
Prepaid expenses and other assets	25	25	1,260	3,000	1,800	2,000	2,000	2,265	2,265	2,265	2,265	2,265	2,265	2,265	2,265
Total Current Assets	12,409	21,030	26,912	38,384	37,233	28,542	28,542	29,149	24,535	20,431	24,595	24,595	19,467	17,133	36,377
Restricted cash	141	141	141	141	141	141	141	141	141	141	141	141	141	141	141
Property and equipment, net	23	19	23	17,156	15,152	21,281	21,281	21,521	22,411	22,999	22,987	22,987	22,977	22,967	22,957
Other long term assets	-	32	33	6,000	6,000	6,000	6,000	100	100	100	100	100	100	30	30
Total Assets	12,573	21,222	27,109	61,681	58,526	55,964	55,964	50,911	47,187	43,671	47,823	47,823	42,685	40,271	59,505
Liabilities, Conv. Stock & Stockholders' Equity															
Current Liabilities															
Accounts payable	225	761	2,408	1,096	346	553	553	989	968	856	676	676	1,140	2,100	5,400
Accrued expenses	396	1,361	1,014	300	250	150	150	150	150	200	200	200	570	570	570
Deferred Revenue	-	800	800	-			-					-			
Other liabilities	68	562	604	604	604	20	20	20	20	20	20	20	20	20	20
Total current liabilities	689	3,484	4,826	2,000	1,200	723	723	1,159	1,138	1,076	896	896	1,730	2,690	5,990
Other long term liabilities	-	96	109	100	100	100	100	100	100	100	100	100	100	100	100
Loan Payable	-	-	4,929	4,929	4,929	4,929	4,929	4,929	6,179	7,429	8,679	8,679	13,679	16,679	17,679
Total liabilities	689	3,580	9,864	7,029	6,229	5,752	5,752	6,188	7,417	8,605	9,675	9,675	15,509	19,469	23,769
Convertible preferred stock	22,155	39,197	41,952	41,952	41,952	41,952	41,952	41,952	41,952	41,952	41,952	41,952	41,952	41,952	41,952
Stockholders' Equity															
Common stock	-	2	2	39,675	39,675	39,675	39,675	39,675	39,675	39,675	39,675	39,675	39,675	39,675	39,675
Additional paid in capital	303	653	794	1,094	1,694	2,294	2,294	2,894	3,494	4,094	4,694	4,694	7,297	10,030	12,900
Accumulated deficit	(10,574)	(22,210)	(25,503)	(28,069)	(31,024)	(33,708)	(33,708)	(39,798)	(45,351)	(50,655)	(48,173)	(48,173)	(61,748)	(70,855)	(58,791)
Total stockholder's deficit	(10,271)	(21,555)	(24,707)	12,700	10,345	8,261	8,261	2,771	(2,182)	(6,886)	(3,804)	(3,804)	(14,776)	(21,150)	(6,216)
Total Liabilities, Conv. Stock & Stockholders' Equity	12.573	21.222	27.109	61.681	58.526	55.964	55.964	50.911	47.187	43,671	47,823	47.823	42.685	40.271	59,505

Source: Company reports, JMP Securities LLC



# FIGURE 67. Aratana Therapeutics - Cash Flow Statement

Aratana Therapeutics, Inc.															
Cash Flow Statement															
(\$'s in 000's)															
	2011	2012	1Q'13	2Q'13E	3Q'13E	4Q'13E	2013E	1Q'14E	2Q'14E	3Q'14E	4Q'14E	2014E	2015E	2016E	2017E
Cash Flows from Operating Activities															
Net Loss	(3,464)	(11,636)	(3,293)	(2,566)	(2,956)	(2,684)	(11,498)	(6,089)	(5,554)	(5,304)	2,482	(14,465)	(13,575)	(9,107)	12,064
Adjustments to reconcile net loss to net cash used in operating activities															
Acquired in-process research and development		1,500													
Stock-based compensation expense	26	106	103	300	600	600	1,603	600	600	600	600	2,400	2,603	2,733	2,87
Depreciation	4	13	3	3	4	5	15	10	10	12	12	44	60	60	6
Non-cash interest expense			3				3								
(Gain) loss on disposal of property and equipment			1				1								
Changes in Assets and Liabilities			63	(10,542)	400	(677)	(10,756)	6,071	(21)	(63)	(179)	5,809	834	(2,234)	(2,358
Prepaid expenses	(4)	-	(24)				(24)								
Other assets	(21)	(32)	28				28								
Account payable	(146)	536	713				713								
Accrued expenses	396	965	(654)				(654)								
Deferred income	-	800					-								
Other liabilities	68	(68)					-								
Net cash used in operating activities	(3,141)	(7,816)	(3,120)	(12,805)	(1,952)	(2,757)	(20,633)	592	(4,964)	(4,754)	2,915	(6,212)	(10,078)	(8,548)	12,636
Cash Flows from Investing Activities															
Purchase of property and equipment	(27)	(10)	(8)	(10,615)	(3,000)	(6,134)	(19,757)	(250)	(900)	(600)		(1,750)	(50)	(50)	(50
Purchase of marketable securities	(6,382)	(6,627)	(735)				(735)								
Sales of marketable securities		6,627	735				735								
Purchase of in-process research and development		(1,000)													
Change in restricted cash	(140)	-													
Net cash used in investing activities	(6,549)	(1,010)	(8)	(10,615)	(3,000)	(6,134)	(19,757)	(250)	(900)	(600)	-	(1,750)	(50)	(50)	(50
Cash Flows from Financing Activities															
Proceeds from issuance of Series A convertible stock															
Proceeds from issuance of Series B convertible stock	7,542	7,699													
Proceeds from issuance of Series C convertible stock		8,693	3,406	-	-	-	3,406	-	-	-	-	-	-	-	
Proceeds from issuance of debt			4,927	-	5,000	-	9,927	-	1,250	1,250	1,250	3,750	5,000	3,000	1,00
Proceeds from IPO				39,675			39,675								
Proceeds from stock option exercises		266	97	-	-	-	97	-	-	-	-	-	-	-	-
Proceeds from issuance of restricted stock		139													
Repurchase of early exercised stock			(5)				(5)								
Net cash provided by financing activities	7,542	16,797	8,425	39,675	5,000	-	53,100	-	1,250	1,250	1,250	3,750	5,000	3,000	1,000
Net increase (decrease) in cash and cash equivalents	(2,148)	7,971	5,297	16,255	48	(8,891)	12,710	342	(4,614)	(4,104)	4,165	(4,212)	(5,128)	(5,598)	13,586
Cash and Cash Equivalents															
Beginning of period	8,150	6,002	13,973	19,270	35,525	35,574	13,973	26,683	27,025	22,411	18,307	26,683	22,471	17,343	11,74
End of period	6,002	13,973	19,270	35,525	35,574	26,683	26.683	27.025	22,411	18.307	22.471	22,471	17.343	11.745	25,332

Source: Company reports, JMP Securities LLC



#### JMP FACTS AND DISCLOSURES

## **Analyst Certification:**

The research analyst(s) who prepared this report does/do hereby certify that the views presented in this report are in accordance with my/our personal views on the securities and issuers discussed in this report. As mandated by SEC Regulation AC no part of my/our compensation was, is or will be directly or indirectly related to the specific views or recommendations expressed herein. This certification is made under the obligations set forth in SEC Regulation AC. Any other person or entity may not use it for any other purpose. This certification is made based on my/our analysis on the date of this report's publication. I/We assume no obligation to update this certification to reflect any facts, circumstances or events that may subsequently come to my/our attention. Signed J.T. Haresco and Ralph Fong

## JMP Securities Disclosure Definitions:

JMP Securities currently makes a market in the securities of Aratana Therapeutics, Inc. and Allergan, Inc.

JMP Securities was manager or co-manager of a public offering for Aratana Therapeutics, Inc. in the past 12 months.

## **JMP Securities Investment Opinion Definitions:**

Market Outperform (MO): JMP Securities expects the stock price to outperform relevant market indices over the next 12 months.

Market Perform (MP): JMP Securities expects the stock price to perform in line with relevant market indices over the next 12 months.

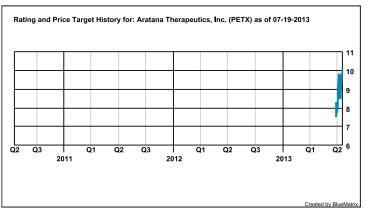
Market Underperform (MU): JMP Securities expects the stock price to underperform relevant market indices over the next 12 months.

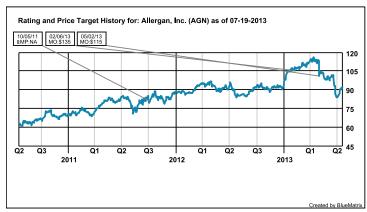
JMP Securities Research Ratings and Investment Banking Services: (as of July 19, 2013)

							# Co's Receiving IB	
		# Co's	%		# Co's	%	Services in	% of Co's
	Regulatory	Under	of	Regulatory	Under	of	Past 12	With This
JMP Rating	Equivalent	Coverage	Total	Equivalent	Coverage	Total	Months	Rating
MARKET OUTPERFORM	Buy	236	61.46%	Buy	236	61.46%	72	30.51%
MARKET PERFORM	Hold	141	36.72%	Hold	141	36.72%	21	14.89%
MARKET UNDERPERFORM	Sell	7	1.82%	Sell	7	1.82%	0	0%
TOTAL:		384	100%		384	100%	93	24.22%

## **Stock Price Chart of Rating and Target Price Changes:**

Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. In accordance with NASD Rule 2711, the chart(s) below reflect(s) price range and any changes to the rating or price target as of the end of the most recent calendar quarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.





## **Aratana Therapeutics, Inc. (PETX)**



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