# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

	SECC	Washington, D.C. 20549	SION	
		FORM 8-K		
		CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934		
	Date of Repo	ort (Date of earliest event reported): Ma	rch 20, 2014	
	(Exact	ADVAXIS, INC. name of registrant as specified in its ch	arter)	
	<b>Delaware</b> (State or other jurisdiction of incorporation)	<b>00028489</b> (Commission File Number)	<b>02-0563870</b> (IRS Employer Identification No.)	
305 College Road East Princeton, New Jersey (Address of principal executive offices)			<b>08540</b> (Zip Code)	
Reg	gistrant's telephone number, including area code: (609)	452-9813		
	eck the appropriate box below if the Form 8-K filing is visions (see General Instruction A.2. below):	intended to simultaneously satisfy the filin	g obligation of the registrant under any of the following	
	☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)			
	Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)			
	□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))			
	Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))			

#### Item 7.01 Regulation FD Disclosure.

On March 20, 2014, Advaxis, Inc. (the "Company") and Aratana Therapeutics, Inc. ("Aratana") hosted a conference call to discuss the Exclusive License Agreement that the Company and Aratana entered into on March 19, 2014. A copy of the transcript of the conference call is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 7.01 by reference.

The information furnished pursuant to this Item 7.01, including Exhibit 99.1 hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities under that Section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

#### Item 9.01 Financial Statements and Exhibits.

The following exhibit is filed herewith:

(d) Exhibits.

Exhibit No. Description

99.1 Advaxis, Inc. and Aratana Therapeutics, Inc. Conference Call Script

#### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

## ADVAXIS, INC.

By: /s/ Daniel J. O'Connor

Name: Daniel J. O'Connor
Title: Chief Executive Officer

Date: March 24, 2014

## EXHIBIT INDEX

# Exhibit No. Description

99.1 Advaxis, Inc. and Aratana Therapeutics, Inc. Conference Call Script

Event ID:

Event Name: Aratana and Advaxis Licensing Agreement Conference Call

Event Date: 2014-03-20

Officers and Speakers

Dr. Steven St. Peter, Aratana Therapeutics, President and CEO

Dan O'Connor, Advaxis, President and CEO Dr. Robert Petit, Advaxis, Chief Scientific Officer

Operator: Good morning, and welcome to the Aratana and Advaxis conference call. (Operator instructions) Please note that this event is being recorded. Now, I would like to turn the conference over to Joshua Drumm. Mr. Drumm, please go ahead.

Joshua Drumm: Thanks. Hello and thank you for joining us this morning. In a few moments I will hand the call to Dr. Steven St. Peter of Aratana Therapeutics, who will introduce today's speakers and provide an overview of the licensing agreement that was announced this morning in a joint press release from Aratana and Advaxis. Copies of the press release are available on each company's respective websites.

Please note that the speakers on this call will be making some forward-looking statements today. These statements involve uncertainties and risks, and therefore should not relied upon as predictors of future events. Actual events and circumstances may be beyond the company's control and may differ materially from those stated or implied by today's forward-looking statements, including but not limited to, as a result of the risks, uncertainties and other important risk factors set forth in Aratana and Advaxis's respective filings with the SEC.

This conference call also contains time-sensitive information that is accurate only as of the date of this live broadcast, Thursday, March 20<sup>th</sup>, 2014. Aratana and Advaxis undertake no obligation to revise or update any forward-looking statement for expected events or circumstances after the date of this conference call. Now I would like to turn the call to Steven St. Peter, you may go ahead, Steven.

Steven St. Peter: Good morning, this is Steven St. Peter, President and CEO of Aratana Therapeutics. I'm here today with several members of each of the Advaxis and Aratana team. Welcome to our call to discuss what we believe will be a tremendous collaboration to improve the lives of pets stricken with cancer, as an important innovative therapy moves forward in humans.

We're very pleased to announce that we have entered into a strategic development agreement with Advaxis, whereby we have licensed their immunotherapy for use in osteosarcoma in pets. In addition, we have licensed three additional immunooncology products for development in other cancers. We believe that this immunooncology platform complements our monoclonal antibody platform, and it fits squarely within a core therapeutic focus at Aratana: oncology. This collaboration is rooted in a shared passion for bringing innovative solutions forward to address serious medical diseases, and a dedication to improving the lives of others.

While the formal relationship between the companies is new, the individuals' paths have overlapped at multiple points. I am pleased to introduce Advaxis's president and CEO, Dan O'Connor, who will explain how we came together and will provide details on the agreement. And for those Aratana shareholders on the call who don't know Dan, he came to Advaxis with significant oncology experience, having worked on a landmark monoclonal antibody, Erbitux. Dan.

Dan O'Connor: Thanks, Steven. As Steven mentioned, I've spent a large portion of my career in oncology. I came to Advaxis because I recognized the potential of cancer immunotherapy, which is perhaps the most exciting area of cancer research in years - in fact, it was the *Science* magazine breakthrough of the year in 2013. As many of you know, conventional treatment methods for cancer, such as chemotherapy and radiation, have reached a ceiling in terms of improving treatment outcomes. We believe that our immunotherapy program is unique, which is why we are attracting the interest of partners.

Back in October, when we began showing the statistically significant canine osteosarcoma survival data to biotech-focused investors in advance of our large capital raise, repeatedly, investors mentioned one company to us for considering partnering with: that company was Aratana. I am grateful that these investors recognized the potential value of placing our immunotherapy in the hands of a premier pet therapeutics company with a global reach and dedicated focus on oncology.

After initial meetings with Aratana, we became convinced that they were the right company to develop our immunotherapies in pets, based upon their track record, their existing pipeline, their knowledge of the oncology market, and their teams' familiarity with our immunotherapy. Dr. Laura Tremel, who is responsible for development in oncology at Aratana, was a colleague of Dr. Nicola Mason, the investigator on the canine osteosarcoma clinical trial at the University of Pennsylvania, and she also worked in our founder's lab at UPenn. And mutual respect is always a good starting point in a long-term collaboration.

Now let me review the terms of the deal announced this morning. The key financial terms of the agreement can be summarized as follows: first, Advaxis will receive \$2.5 million upfront, with \$1 million of that upfront payment in cash, and a \$1.5 million equity investment at current market price. Second, up to \$52.5 million in aggregate approval and sales milestones for all four products in the US and EU territories, and for dogs and cats. Up to \$6 million per product in developmental milestones, plus up to \$28.5 million in commercial milestones. Third: a tiered royalty ranging from mid-single digit to 10 percent on net sales. With nearly six million dogs and six million cats being affected with cancer each year just in the United States, we believe that in the coming years, the milestones and royalties from four potential oncology products in two species could be a meaningful addition toward funding our human developmental program. I'm delighted that we were able to construct such a creative, multi-product, multi-specie deal that we both believe is a major milestone for us, our shareholders and companion pets.

Now I'd like to introduce Dr. Robert Petit, Chief Scientific Officer of Advaxis, who will explain why immune-oncology, and the Advaxis platform in particular, is so exciting to both companies. Robert.

Robert Petit: Thank you, Dan. I've spent over 20 years in immunotherapy and oncology research, and prior to coming to Advaxis I was at Bristol-Myers Squibb. At BMS I was the US medical lead for Yervoy, the most recently approved immunotherapy for cancer in humans. The fundamental challenge in the immunotherapy of cancer is to get the body's immune system to recognize and reject tumors that by definition, it's already been tolerating. In order to do this, it's necessary to access and direct the dendritic cells to generate a large number of cancer-fighting T-cells, as well as to override or bypass mechanisms of immune tolerance that have been protecting the tumor thus far, especially inside the tumor microenvironment where T-cells literally have to do hand-to-hand combat with the tumors to get rid of them. This last point is hugely important, and the Advaxis platform is the only one I've seen that can really accomplish this. Our treatments do all of these things in a very unique way, by borrowing from a pathway that already exists in nature to eliminate certain bacterially infected cells. Advaxis immunotherapies actually make and secret critical tumor antigens from inside the immune system, like a Trojan horse, and cause the immune system to know see the tumors as infected cells, and then coordinate their elimination. Other therapies are trying to piece this all together one element at a time, but the Advaxis approach takes a process that already works and adapts it to fight cancers without having to reinvent the wheel.

Our first immunotherapy has been shown to prolong lives and eliminate tumors in clinical trials for women with human papillomavirus associated cervical cancer; but HPV isn't exclusively a human problem. In many cases, the causes of cancer in our pets are the same ones that afflict us as humans. As an example of this, HER2 over-expression is well known to cause breast, stomach, esophageal and other cancers in humans; it's also known to cause bone cancer in dogs. Our Advaxis HER2 immunotherapy research has been pioneered in canine osteosarcoma by Dr. Nicola Mason, who has generated some truly impressive data in this naturally occurring and devastating cancer. Her data shows this well-tolerated immunotherapy can truly prolong the survival of dogs suffering from this fatal bone cancer in a very significant way. Based on this data, we recognize the need to accelerate our treatment programs in humans so that the people we love with these cancers can see the same benefit that Nikki has been showing in the pets that we love. I'm pleased to turn the call over now to Nikki, who can discuss those results.

Nicola Mason: Thank you, Robert. I'm Dr. Nicola Mason, I'm an assistant professor of medicine and pathobiology at the University of Pennsylvania School of Veterinary Medicine, and I'm the principle investigator of the study that Advaxis is sponsoring to evaluate the Advaxis cHER2 vaccine in pet dogs with osteosarcoma, which is a very aggressive bone cancer. The results that I've seen so far in the dogs that I have treated have exceeded what I could have hoped for in these dogs that have such an aggressive disease. I am really excited by the fact that this treatment now have the potential to become commercially available, so that all dogs that are affected by this disease can now benefit from this therapeutic advance.

To recognize the need for new and effective treatment for osteosarcoma, I think it's important to understand the disease. Osteosarcoma affects 8,000 to 20,000 dogs a year in the United States alone. It is a highly aggressive tumor that affects the long bones of large and giant breed dogs. The standard of care for these dogs is amputation of the affected limb, followed by chemotherapy; and the chemotherapy is aimed at delaying the inevitable appearance of metastatic disease. But despite amputation and chemotherapy, the median survival for these dogs is 10 to 12 months, and most of these dogs die from pulmonary metastatic disease.

At Penn, as a result of this clinical trial, I see a lot of dogs that have been diagnosed with osteosarcoma. Unfortunately, the treatment options are relatively limited, and it is always difficult to tell owners that despite our best efforts using standard of care treatment, the long-term prognosis for their dog is very poor. It's really not surprising that these owners are always interested to hear about and to pursue a new therapy that could increase their dog's overall survival.

The study we performed at Penn started in 2012. Our first dog was diagnosed with osteosarcoma in March of that year. As a clinician, my first impression was surprise at how benign the therapy is with respect to side effects. The dogs have a mild fever and some nausea on the day of vaccination, and then they go home the same night and eat their dinner. We re-evaluate these dogs every two months, and we have not observed any long-term side effects. The dogs vaccinated with the Advaxis cHER2 vaccine have shown a statistically significant prolonged survival, compared to dogs that received standard of care treatment without the Advaxis immunotherapy.

Now there's a lot of public interest in this trial, as it has important implications for both humans and dogs with this and other diseases. So to keep owners and veterinarians up to date, I posted the early results on Penn's Facebook page, and within the day we received an overwhelming response from pet owners in this country and around the world. Both owners and veterinarians wanted to know how to get this immunotherapy for their pets, and how their pets could participate in the study. I think that this response demonstrates the level of interest by both the general public and the veterinary profession in a promising new treatment for an otherwise fatal disease.

Just to summarize what we have found so far in our study: the results showed that pet dogs with osteosarcoma treated with the Advaxis cHER2 immunotherapy after standard of care have a statistically significant prolonged overall survival with a P value of 0.032, compared with dogs that received standard of care without the Advaxis immunotherapy. The median survival for dogs that did not receive the Advaxis cHER2 vaccine was eight months, whereas the median survival time for dogs treated with the Advaxis cHER2 vaccine has not yet been reached. The first four dogs treated are still alive, with survival times over 21 months - that's well beyond the life expectancy of these dogs. The majority of treated dogs are tumor free. From a safety standpoint, only low-grade toxicities, consisting of a mild fever and brief nausea or vomiting on the same day as administration, was seen. There have been no long or short-term complications observed with the immunotherapy.

I'm excited that Advaxis has licensed its immunotherapy to such a strong animal health partner that is focused on bringing this promising and unique immunotherapy into the veterinary arena, and I'm very keen to explore other opportunities with Aratana, using the Advaxis platform technology. The platform has a lot of potential, and I'm excited about the prospects of this approach in the treatment of highly prevalent cancer types, such as lymphoma and hemangiosarcoma. I would now like to turn the call over to Dr. Linda Rhodes, the CSO for Aratana, who will briefly discuss their development plans. Linda.

Linda Rhodes: Thanks, Nikki. We are very excited to have the opportunity to develop and commercialize these innovative products, which are really a great complement to our antibody portfolio. As those of you who follow Aratana know, our antibody products for oncology are regulated by the USDA, and we believe that these immunooncology products will also be regulated by the same government organization.

Under the USDA process, some biologics can achieve a conditional license status at about three years, and given the existing data set that Dr. Mason mentioned for osteosarcoma, we believe our timelines, and hence, development costs, will be lower for our first product and consist mainly of manufacturing cost to Aratana. Upon completion of this deal, Aratana will assume responsibility for work with Dr. Mason and other veterinary oncologists on the second program, and we expect to provide further details on additional programs in the future.

One of the most exciting aspects of immunooncology in humans has been using these products as combination therapy with monoclonal antibodies, which have the potential to extend life by having a greater affect on tumor burden than antibody therapy alone, or in combination with chemotherapy. And while these regiments are in early days of testing in humans, we will be watching for clues, and the favorable cost of goods of both of our product platforms would certainly make this a longer term for pet therapeutics. With that, I'd like to turn over the call to back to the operator to open the lines for Q&A - operator.

Operator: Yes, thank you. We will now begin the question and answer session. (Operator instructions). And the first question comes from Douglas Tsao with Barclays.

Douglas Tsao: Hi, good morning. You know, Steven, first off, if you could provide some perspective with the long time of vet therapeutics, you've obviously been very active in terms of building up your oncology portfolio. You know, what is it necessarily about this therapeutic area that is particularly exciting to you right now, versus what sort of I guess I would characterize as sort of more typical primary care therapeutics for companion animals.

Steven St. Peter: Right, so thanks, Doug, and good morning, thanks for joining. You know, so oncology is one of the therapeutic areas that we're very focused on; in fact, our initial commercial effort will be in oncology, and the reason that we're excited about it is one, you know, according to the Morris Animal Foundation, up to a third of dogs will get cancer, and actually up to half over the age of 10 will die of cancer; so it's a really, area of big unmet medical need, and it really is truly a specialty area. So, there's about 300 boarded vet oncologists in the United States, which are part of a group of about a thousand veterinarians who focus really exclusively in oncology. So, there's a ready network of oncologists who are really wanting additional therapies and will work with companies like Aratana to help develop these products, and then ultimately bring them to the market. And so, we love the fact that it's such a concentrated group of folks that we can start on, and we also like oncology, you know, certainly in its own merits but it fits very nicely with some of the other products that we are developing and hope to have approvals as early as 2016. Our inappetite program, our AT-002 for inappetents, you know, you see that in oncology; our AT-003, our liposomal depobupivacaine product - that oncologists frequently do surgeries and those surgeries tend to be painful. So we think it's a great and very capital-efficient place for us to start, and it really allows us as we become a generalist company to roll that out.

Douglas Tsao: Okay great, and then, as a follow up, could you perhaps provide a little perspective. Obviously, the initial clinical data that Dr. Mason generated at UPenn is very promising - provide a little perspective on, sort of on how you're seeing the development pathway right now for this product?

Steven St. Peter: Well, you know, so Doug, in this, I think, allows us to talk again about a fundamental tenet of how it works with the USDA. I mean, at Aratana, we deal with both the FDA for certain drugs, typically small molecules, and the USDA Center for Veterinary Biologics with large molecules; and while we're all familiar with the rigorous randomized placebo controlled trials that the FDA typically requires, the USDA allows you with, you know, dozens of patients to submit data and get a conditional license, and then you can actually really work with oncologists in this case to define, ultimately, the way that this product is going to work, and where exactly it's going to fit within the practice. I think on the FDA side, it's really up to the sponsor company to run the trials to show that and put it in the label and then promote within the label. I mean, for instance, our conditional license with the USDA on our lymphoma products reads, 'an aid in the treatment of lymphoma.' So, you know, it's a very broad license, and you've got to work with the oncologists to figure out how it fits into the practice. So, similar to our lymphoma franchise with the monoclonal antibodies, the commercial roll out is much slower because you're really finishing clinical development and defining where it's going to fit in the practice, and publishing, with key opinion leaders, data to help guide the oncologists. So, and with respect to this product, you know, similar. We have a substantial amount of data, as Dr. Mason summarized, that can be presented to the USDA. You know, we need to figure out if that's going to be our submission for a conditional license or we'll do more work before we submit the product. And we've got to do manufacturing, you know, the USDA is obviously very inappropriately focused on manufacturing, but once we get through that we can make a submission and potentially get a conditional license, and then as, you know, take it to the market and then ultimately finish a regulatory trial to result in the full l

Douglas Tsao: Okay, great, thank you very much.

Operator: Thank you. And the next question comes from Tim Lugo with William Blair.

Tim Lugo: Thanks for taking my question, and congratulations on the in-licensed products, they seem very interesting. Can you talk about the timing of the additional product candidates outside of osteosarcoma, and I believe Nikki might have mentioned lymphoma - is that one of the three other products in-licensed?

Steven St. Peter: Yeah, so, you know, we're not talking at this point about which other areas we've in-licensed the technology to use in terms of other cancers, but, you know, they are big and important diseases. We want to do that work and make sure we, we've captured, you know, certainly from an intellectual property but also from a competitive perspective, to kind of know where we're going. So I'm sorry, you know, Tim, I'm not gonna answer your question on the other product areas, but they are defined in the license and we and Advaxis understand what they are; but we're talking about osteosarcoma as the one that we're pursuing first.

Tim Lugo: That's fine, and I believe there was a mention of 8,000 to 20,000 dogs with osteosarcoma a year - that seems like a wide range. Is it an underdiagnosed disease, is it, you know, how many are treated - can you maybe expand upon that a bit?

Steven St. Peter: Yeah, so I'll take that. So, you know, data in the pet market with respect to medical diseases and incidences is quite varied; I mean, we have seen that with all of our products and so I think we, through our primary market research, are beginning to establish the size of these markets. I mean, the problem is, these diseases tend not to be diagnosed, and when they are diagnosed, a lot of times they're not treated; and the reason for that is 'cause simply there's not really good therapies. So, we think as we bring therapies forward and create awareness of the fact that there are safe and effective therapies, you'll actually, you know, collect better data. But the absence of payers in this market, the absence of government in this market, and the absence of, you know, really organized, you know, pharmacies in this area really creates a sort of lack of data, that what we do believe that there is a substantial number of dogs that, that are affected with osteosarcoma and, again, apologies for how wide the range is, but that's just part of the kind of the pet therapeutics situation.

Tim Lugo: Oh, that makes sense. And actually, on a last question, can you talk about the development time frame, I think goes on three years for a conditional approval - is that three years from let's call it Q2 2014?

Steven St. Peter: So, what we've said before, and I think Dr. Rhodes summarized it was, it's kind of two to three years when you're dealing with the USDA to get a conditional license. So, obviously, you know, Dr. Mason has been doing work here on the product and generating some data, you know, for a couple of years; so we're well into the timeline, but we're not on this call as Aratana articulating when we actually will submit for a conditional license and the timeline on when that's gonna work - but we will be giving guidance on that, Tim, as we go forward. I mean, Aratana has over 15 products in development now, and, you know, we will do a development day this, you know, maybe in conjunction with - well, we'll do a development day at some point here and really review all of our programs and I think as you know, we, we're very telepathic about putting dates out there when we've decided them, and we will be doing that with this product. But we want to get our hands around it and make sure we, you know, we really understand it and we, as Aratana, will be articulating the timeline on a kind of a go-forward basis. But it's, you know, we believe within that two to three year window, obviously, and we've already started.

Tim Lugo: Understood.

Operator: Thank you. And the next question comes from Rahul Jasuja from Nobel Capital Markets.

Rahul Jasuja: Yeah, good morning guys, and congratulations on the, on the transaction. My question's really based on getting a better understanding on animal versus human, you know, immunotherapy, so to say. So the question I had, and maybe it's for Robert and Nikki Mason here, is that *Listeria* is known to have evolved with human beings and you can harness the infectious cycle of *Listeria* for immunotherapy it has been done; but how does it pertain to canine or dog in terms of, what is the relationship and does *Listeria* in the construct that is used with the cHER2 have a similar immune response? Could you just comment on that?

Robert Petit: Sure, this is Robert Petit, I'll start it and maybe turn it over to Nikki a little bit. You know, the mechanisms of the oncogenesis here for HER2 driven malignancies are exactly the same, in fact, there's a 90 percent sequence homology in the HER2's peptide between humans and canines, and so it's very analogous, and *Listeria* is really all around us in, in our environment, and infects all major animals, including humans, including dogs, including other animals, and these animals living in its environment have to have all developed the same sort of immunologic pathway to protect against these infections, that we're taking advantage of to turn that over to treat the cancers, and you know, Nikki has done some tremendous work at characterizing the HER2 expression level in these dogs, and maybe she could speak a little more about that.

Nicola Mason: Yes, we certainly do see evidence of HER2 expression probably in 80-85 percent of these dogs with osteosarcoma. The immunological response to the vaccine is basically, is seen by increasing levels of white blood cells, so we do see increasing neutrophil\_counts following vaccination, we do see fever which is a cytokine release associated, and there's really no reason to believe that the immunological response that the dog produces in response to the *Listeria* vaccine should be any different from that, that's produced by humans when they receive the *Listeria* vaccine, too. So, everything that we have seen so far follows the effects that are seen with the HPV *Listeria* in people.

Rahul Jasuja: Great, and then my last question really stems from my, I guess my ignorance about the animal healthcare market and the process. Are there a lot of cases where drugs, or a few patients, rather, where drugs that have been approved in animals then go to human beings, or vice versa - the drugs are approved in human beings and then going to dogs. So, I have no clue how that, if there is a historical case on that.

Steven St. Peter: Yeah, so Rahul, let me take that and we really welcome all the Advaxis investors and analysts who are here and getting their first kind of exposure to the pet therapeutics opportunity. And so, just at a very high level, and we can spend as much time with you as you would like on this or anyone else on the call, you know, in terms of how it works. But really, the pet therapeutics market is, is a new opportunity. I mean, historically, pets who lived outside the home and weren't considered family members have really moved into the home and are considered family members; and so they are living longer, and as they're living longer they're manifesting many of the same medical diseases that their human counterparts get. But unfortunately, the animal health industry traditionally is a food animal industry focused on production animals like cattle and swine, whereas the pet market they've typically done flea/tick/heartworm vaccines, but they've never thought about family members as, you know, needing their medical needs addressed.

And so that's what really Aratana brings to the table. So the sad reality for pets is that over 90 percent of the medicines that veterinarians used have never been shown to be safe and effective in pets; in fact, chemotherapy, which we believe is used, you know, over a hundred thousand times a year in the United States on dogs, has never been approved in dogs - yet, it gets used, you know, quite frequently. So, our value proposition then is to change that by actually doing the safety and effectiveness studies to show that these products work, and work with the regulatory authorities to actually get labels.

And so just to close and put a fine point on the level of innovation out of the animal health industry, in 2011, 12 and 13 - so, three years - you know, the U.S. FDA approved four new chemical entities in three years in the combined species of cats and dogs: four. And you know, as I mentioned earlier, we have over 15 products in development, so we're changing the game in terms of bringing innovation to the pet market, and we think that pet owners, you know, desire that and we think veterinarians would love to offer therapies shown to be safe and effective.

Rahul Jasuja: Great, that's helpful, thank you.

Steven St. Peter: You know, just one other comment just to give you an example of that is, you know, in this case, in a way, you know, dogs will see this therapy obviously before humans, although concurrently, Advaxis is working in humans. We expect to get an approval in dogs, you know, before I think humans; but our other product that we mentioned earlier, the lymphoma products - I mean, rituxan has been widely used in humans, and rituxan is an anti-CD20 monoclonal antibody directed at human, you know, CD20; and if dogs have B-cell lymphoma, they have the CD20 marker, but you can't use a human protein against a dog CD20, because it's not optimized for that dog CD20, and it's also immunogenic. So at Aratana, we've developed a monoclonal antibody against CD20 for dogs, and that product has been conditionally licensed by the USDA, and we've done a similar thing with anti-CD52 - CAMPATH for T-cell lymphoma. So, you know, there's, to your question - there's definitely situations where human diseases and biology can be then replicated in a species-appropriate way, and we've already started to do some of that.

Rahul Jasuja: So there's actually a process where you can, as you humanize antibodies for human beings, you can, I guess animalized antibodies for dogs?

Steven St. Peter: Yeah, so we call it canine-eering and feline-eering, and we do that, and we've already had two conditional licenses issued by the U.S. Department of Agriculture for those technologies. So, you know, this is a, one of our, a company we bought in October called Vet Therapeutics pioneered that, and we believe has some, you know, crucial IP in the space, and we are rolling out a monoclonal process, you know, in lots of areas - and cancer, obviously, is a huge area for that, and one of the secrets about this is, because it's not regulated by the FDA, the GMP manufacturing requirements are not there. Now, USDA has very strict and appropriate manufacturing guidelines, but they're different, and because they're different we believe we can achieve pharmaceutical margins on these products. So the, the issues of making, you know, human monoclonals in GMP environment, you know, we're not, that's not the situation that we deal with when we're with the USDA.

Rahul Jasuja: Thank you.

Operator: Thank you, and the next question comes from Jon Block with Stifel.

Ethan Roth: Hi, good morning, this is actually Ethan Roth, on for Jon Block. Maybe just two questions to start for Dr. Mason. First, how do you envision immunotherapy ultimately being used in a commercial setting, and does this have the potential to openly displace standard of care for pet owners who maybe are looking for alternative to either amputation and chemotherapy?

Nicola Mason: We have not done those studies yet, but certainly that is something that I think is possible, and it's something that we're looking into.

Ethan Roth: Okay, great. And just the second question, can you just talk about the quality of life for a dog receiving standard of care treatment, and if you think immunotherapy has the potential to improve that quality of life.

Nicola Mason: Yes, I certainly can, and as I said, we've obviously seen a number of dogs coming through that have standard of care amputation and full-up chemo. The majority of dogs do very well with amputation, as long as they're not huge, and very heavy up at the front end, in which case a full limb amputation sometimes is problematic. Chemotherapy is relatively well tolerated in dogs following amputation. The problem is that despite the treatment, the amputation and the chemotherapy, they still relapse with metastatic disease, and that may be in part because our doses of chemotherapy that we use are lower than perhaps is used in the human field, and we do that deliberately so that we don't make the dogs sick, and we have a good quality of life even though they are undergoing chemotherapy. With this Advaxis vaccine, as I said before, we've really seen very few side effects, and the only ones are following within several hours of administration - they're mild fevers and some nausea and vomiting, and by the end of the day these dogs are normal. So, quality of life for these dogs following immunotherapy is remarkably good. So I expect to continue to see that with these immune therapies.

Ethan Roth: Okay, great, thanks, that's all for me.

Operator: Thank you. And the next question comes from Charles Haff of Craig-Hallum. Please go ahead, Mr. Haff, your line is live.

Charles Haff: Oh yes, sorry. Most of my questions have been asked and answered, but regarding the stage of development for the other three targets, I appreciate that you don't want to tell us what those targets are for competitive reasons, but could you maybe describe at what stage of development those targets are?

Steven St. Peter: Well, you know, I'll comment on that. You know, in the sense that, you know, they're obviously far enough along that we specifically called out those areas in the license, you know, so it's not like they're, they're at concept stage, but, you know, we're working to figure out how to move those forward and I think that's just all we're gonna comment on, you know, with respect to this call.

Charles Haff: Okay, thank you.

Operator: Thank you. And the next question comes from Jose Haresco with JMP Securities.

Jose Haresco: Hi, guys, good morning, and congratulations on the really incredible pipeline expansion again. This is kind of a follow-up question to a comment that was made earlier, but given the homology between human genes and canine genes, does it make sense or is there an opportunity to explore molecular diagnostics for canines, given all the breakthrough that we're seeing on the human side, and, finally, the price of sequencing coming down so much, and in terms of being able to employ a more targeted approach in treating cancer in dogs.

Steven St. Peter: Yeah, you know, Jose, so why don't I take that and if they guys at Advaxis want to add on, that'd be great. But, so from Aratana's perspective, I think you'll recall that, you know, we actually have a diagnostic, you know, to help differentiate between the B-cell lymphoma and the T-cell lymphoma dogs, because the treatment's gonna be different and the clinical presentation doesn't allow you to differentiate. And we've said that we will seek larger partners to help, you know, we developed the diagnostics as part of the development strategy, but obviously, commercially, those are gonna be important, too, and we will seek partners to work with us to, you know, bring along those diagnostics and, you know, with these technologies, you know, similarly, both in diagnosing and monitoring therapy, we think there is a diagnostics opportunity, but that's not an Aratana opportunity other than partnering with a large company and working, you know, closely with them.

Robert Petit: Right, and this is Robert in Advaxis. You know, and what I can say is that, you know, certainly in the human situation, diagnostics have become hand and glove, part of the future of cancer treatment as we continue to exploit the Achilles heel of this particular tumor over another, and the Advaxis therapies are targeting just exactly those things that are characteristic of certain malignancies, and for this trial, Nikki Mason was not only treating the patients, she was also doing the diagnostic work and I think that, you know, as the immunotherapy of canine and pet malignancies increases, then there'll be a need for expansion of the diagnostic market as well. Nikki, would you like to comment on that?

Nicola Mason: I don't have too much more to add to that, but I think that certainly you are, we are seeing currently people exploring molecular diagnostics in dogs, so, I think you're gonna see that coming up and that's gonna direct therapy, and particularly, the immunotherapy.

Jose Haresco: Great, thank you very much.

Operator: Thank you. And the next question is from Ram Selvaraju with Aegis Capital.

Ram Selvaraju: Thanks so much for taking my questions, I just have three quick ones. Firstly, could you comment on, and I guess this is for both the Aratana and the Advaxis team - the possibility of combining checkpoint and division strategies with the Advaxis cancer immunotherapy approach, and what evidence has been seen thus far, whether that's of the human or the animal context, of synergy between those two approaches and if that is something that Aratana, you plan to explore more stringently going forward as part of your overall push into cancer immunotherapy in the veterinary health space.

Dan O'Connor: Ram, hi, this is Dan, that's a great question, thanks. Steven, maybe you could take the first part of it and, vis-à-vis the animal health, and Robert can answer the question for human therapeutics.

Steven St. Peter: Yeah, so, thanks Ram. We, we agreed checkpoint inhibitors, you know, are interesting biology and we certainly are looking at those. We have not announced that as part of our portfolio, and you know, we tend not to announce that we're specifically working on things until they're actually in development. You know, other companies like to talk about concepts - we tend to like to talk about products, so, I think I'll just leave it at that.

Robert Petit: Right, and to expand on your question from a more general sense, Ram, you know, clearly, you know, as I said in my statement earlier, the issue with cancer immunotherapy is really one of overcoming tolerance, and there are a couple of critical mechanisms of tolerance that are involved in protecting tumors. One of those is around peripheral tolerance, from which the checkpoint inhibitors are being developed as interventions. CTLA4, the drug I worked on at BMS, and PD1 is all the rage right now in a number of human clinical trials - those all modulate a particular interaction about, that's inhibiting the expansion of T-cells. So beyond that, once those T-cells get into the tumor microenvironment, they also have to overcome elements of central tolerance that are mediated by myeloid suppressor cells and regulatory T-cells that secrete sort of clouds if you will of, of inhibitory molecules like IL10 and TGF-beta, and arginase-1 that shut down any activated T-cell in the tumor microenvironment. The interesting aspect of the Advaxis platform is that in addition to providing the antigen-specific T-cells needed to kill the cancer, this platform knocks down the suppression mediated by T-regs and myeloid suppressor cells in the tumor microenvironment. We've recently published some data in collaboration with an investigator that showed a synergy with a PD1 checkpoint inhibitor and the Advaxis platform, where each provides what the other may be missing as part of the treatment. And so the Advaxis makes certain that cells are there and that when those cells get to the tumor microenvironment, the defenses of the cancer have been neutralized, but the checkpoint inhibitor amplifies the number of T-cells that are generated to fight against the cancer, and so the two things really partner very well together. So, that's really theoretic, and that's being developed in the experimental stages now but, because they're synergistic mechanisms of action, we look forward to future development.

Robert Petit: Yeah, Ram, I'll just augment a little bit. So, you know, we're beyond the theoretical, we're into the pre-clinical showing clinical data, and that was Dr. Samir Khleif, published that data. And so we're looking on building on that data and exploring the synergy which we've already seen pre-clinically with other PD1 antibodies; so that's definitely on our, on our to-do list this year. Thanks for the question.

Ram Selvaraju: Okay, and then secondly, with respect to strategies for development of the combined Advaxis/Aratana cancer immunotherapy portfolio outside the United States, I just thought maybe Aratana could comment a little bit, give us some color on better understanding of the payment environment outside of the US. Obviously, a lot of us are probably a bit more familiar with how things work in the United States, vis-à-vis private pay and the veterinary health space, and how this works outside of the US; and then maybe give us some information on what the regulatory process is likely to be and how it differs from the process there in the US and what regulatory bodies are involved ex-US.

Steven St. Peter: So, excellent question, Ram. So, you know, just on following up on your first question. So, you know, Aratana has a monoclonal antibody platform, and that is the company Vet Therapeutics, and we've developed, you know, several products that are in development now using technology; so we can find targets and develop antibodies against them. And one of the great things about the Advaxis now is, you know, working with them again, looking for those synergies because we bring the canine and feline antibody platform to link up with their technology platform to look at a variety of targets - initially, osteosarcoma; three other targets that we, that we've named in agreement between us, but broader, I think there's a great collaboration opportunity and that, you know, it was great of you to kind of pick up on that.

You know, with respect to the OUS environment for pet therapeutics - so, the way we think about it, the largest market in the world is the United States; the second largest market is Europe, and they constitute actually only about 60 percent of the animal health market and the pet market. And what's interesting about that is, anywhere there's a consumer, there's a pet market, because it's not a government-regulated phenomenon with kinds of bids and tenders; it tends to be really a consumer segment of healthcare, which we think is very attractive. And so, Aratana now, you know, we are, we develop our products in the U.S. through the U.S. FDA and the U.S., the FDA and both the USDA. In Europe, we tend to work with the EMA - there's one regulatory authority that takes on both biologics and small molecules, so you work kind of with the EMA, and we recently in January bought the leading, you know, biotech in Europe called Okapi Sciences based in Leuven, Belgium, and they have a number of portfolio products moving through the regulatory authorities in Europe - two studies underway, actually, field studies in client owned dogs or pets, or, actually, client owned cats or pets. And so we actually at Aratana, we systematically address 60 percent of the market by having a presence in both the U.S. and Europe, but we will seek to partner with the other animal health companies to bring these innovations to other territories, and what's great is if you've done the work in both the U.S. and Europe, extending to other territories is actually quite straightforward.

And in terms of the payment environment, the U.S. it's less than five percent insurance, it's 95 percent private pay. Our big payers is not Aetna and Blue Cross, it's actually MasterCard, Visa and American Express, and you know, there is no pedicare or pedicaid - it is a private pay market. In Europe, it tends to also be a private pay market, although you know, in the UK, about 25 percent of pet owners have pet insurance, and in Scandinavia it's a similar number; but by and large it's still private pay, and where insurance exists, it tends to actually be facilitated as opposed to trying to create barriers to care.

Ram Selvaraju: Okay, and then very quickly, both for the Advaxis and the Aratana teams - I want to pick up on something that Dr. Petit said at the beginning, which was the applicability of the Advaxis platform to areas outside oncology. So, my understanding is that this agreement covers in scope only oncology focused indications. So, first of all, I wanted to ascertain whether that is indeed correct, and secondly, I wanted to ascertain whether there might in fact be a possibility that in future, the scope of this arrangement, this relationship between your two companies, could be broadened to include indications beyond oncology where the Advaxis platform may be applicable, within the veterinary health context, of course.

Steven St. Peter: So you know, I'll start off and get the Aratana perspective, which is, you know, yes, it's focused on oncology at this point, but you know, collaborations take you interesting places, and I think with very passionate individuals working together, you follow where the science takes you, and although the agreement doesn't, you know, doesn't comprehend areas outside of the four specific actually areas that we picked in oncology, you know, that, that's something that obviously in, in forming these collaborations and relationships, we would be interested in because as I mentioned earlier, we're active in many therapeutic categories and diseases.

Dan O'Connor: Yeah, Steven, maybe I'll just briefly add to that. I think, you know, that the disease - the agreement is oncology focused, and the Aratana is, the veterinarian side with Advaxis retaining the human aspects of our platform. I think in terms of the other part, future potential - I think everybody on this call has heard Steve's expertise in answering questions and his team's expertise; so I know that Advaxis is definitely interested in looking to continue the relationship with Aratana.

Ram Selvaraju: Thank you.

Operator: The next question comes from David Moskowitz from Equity IQ.

David Moskowitz: Great, thanks for the question, congratulations to both parties, looks like there's some compelling efficacy data here in osteosarcoma, so congratulations. (Thanks, David). You're welcome. So my question is, let's start with that clinical data in osteosarcoma - tell me from the Aratana perspective, you know, what sort of due diligence gets done here when it comes to the science and the clinical data that you've seen so far.

Steven St. Peter: Why, I am gonna actually turn that over to our chief scientific officer, Dr. Linda Rhodes. Dr. Rhodes actually used to head development at Merial, the largest animal health company at the time, then went on to found the largest animal health focused CRO, which she actually sold and then we recruited her in 2011 to join the team. And she, I think, has worked on essentially every product approved by the U.S. FDA in the last 10 years because of her presence as having built the CRO. So, and, Dr. Rhodes, you might comment on the diligence and kind of the things that you looked at here either specifically or generally, you know, you take that where you want.

Linda Rhodes: Sure, yeah, that's a really good question. We do a very deep dive in due diligence and focus on the areas that are most critical, both for efficacy of the product but also for the little appreciated things like manufacturing and regulatory path, and safety data. So, we did visit Dr. Mason and go through her data in depth; we also did considerable background work on the manufacturing and issued some questions we had around that, and Advaxis have made quite a lot of progress in that area, which is always something that's encouraging to us. So, we engaged an expert who works with the USDA and manufacturing to review the data, in the data, and Advaxis was very generous at opening their data room to us to let us look through all of the work they've done on the human side. So, we did a very deep dive in due diligence, and I think everything we saw led to today; we wouldn't be here if we weren't very impressed with the quality of the science, as well as all the supporting stuff that needs to be there to get approval for a product on the manufacturing side.

David Moskowitz: Excellent, well, thank you for that answer. So, and just on the international side, you know, some questions were asked about the regulatory pathway and payers - what about just market size in general. When, you know, I don't know the animal health business as well either - come from the therapeutic side, so - could you talk to us about what the balance looks like, you know, U.S. market versus ex-U.S.

Steven St. Peter: Yeah, so, we'll do that, David. But you know, I'll also mention that complemented by this was our Dr. Laura Tremel, who is a Ph.D. and a veterinarian - a Ph.D. in immunology, actually, who was from the University of Pennsylvania - she's one of our drug developers based in Kansas City and she, with Dr. Rhodes and our, we have several manufacturing folks, Don Stitzenberg, who worked with Linda, our chief of drug development, Ernst Heinen - so, an entire team of folks scrubbed that down and, and getting to your actual question on the commercial side. So, we match the, you know, the development talent with commercial talent, so, our chief commercial officer, Julia Stephanus, you know, has launched over 25 products including three of the four biggest brands in animal--companion animal health, and you know, previously was, had built and sold a company and was running a companion animal business with the director of the companion animal business for Ceva. So, Julia works with her team to assess the commercial opportunities in both the U.S. and Europe, and the short of it is, that the US is slightly bigger than Europe, but they're they two big markets. And so, you know, I would think about them as, you know, the U.S. being somewhat bigger, but they're both big. And between them, that constitutes about 60 percent of the global market with other markets like, you know, Japan, Australia, New Zealand, even Brazil being important markets. And, and Julia, you know, after she sold the company that she had built, actually worked at her former employer, one of the large animal health companies, to basically, you know, roll out the product throughout Europe and the rest of the world. So, in her most recent job actually, prior to when she joined Aratana more than a year ago was, was taking products from the U.S. and moving them throughout the rest of the world.

David Moskowitz: Great. So, what I heard was, you got Europe, that's kind of a close second to the U.S. and then the rest of the world.

Steven St. Peter: Yeah, and then the other geographies, you know, I would say, are no more than 10-12 percent, but pardon the pun, a lot of cat and dog territories but extremely valuable, and you can approach them very efficiently and there is well developed distributor networks that you can work with there to get the products to those markets. And as I also previously mentioned, from a regulatory perspective if you have U.S. and Europe, you've made a tremendous amount of progress in approaching the other markets. And Dr. Rhodes, you know, having run the CRO that she founded, we also, Dr. Marie-Paul LaChaud, who is in our European organization, she built the largest CRO in Europe, which she sold and she heads, she works with our development team and focuses on Europe. So, you know, there is expertise involved in both the US and Europe, and we have that expertise; and between Dr. Rhodes and Dr. LaChaud, they've also worked on dossiers and I think pretty much every other territory, so we cover it systematically and we try not to leave that value on the table, although from a commercial perspective we certainly are gonna be focused in the U.S. initially and looking at Europe, whether we commercialize ourselves or partner in Europe, you know, over the next 12 to 18 months.

David Moskowitz: Excellent, very, very helpful. And just on the other indications - I know you guys aren't talking that readily about them, but, you know, my question speaks to the technology. Are you able to tell us whether or not there is more than just the HER2 construct from Advaxis - are there more antigens involved than this, or is it just four indications around the HER2 construct?

Steven St. Peter: There's certainly more antigens, and that's what we love about the Advaxis platform and technology and people is they, they are expert in so many important areas of biology, and I think you got that sense today when you heard Dr. Petit answer some questions there.

David Moskowitz: Okay, and just quickly, last question, this is for the Advaxis team, specifically Robert. Can you talk, Robert, about the, I guess the crossover benefits for this type of agreement, and your human immunotherapy programs?

Robert Petit: Yeah, thanks David. You know, the way that we see it, you know, the animal health platform here gives us the opportunity where the mechanisms of oncogenesis are the same - we can work out things in the animal models that will directly inform our human clinical trials, and benefit both the animals and the humans in the process. And you know, with regard to the versatility of the platform, we have already developed at Advaxis over 20 of these constructs targeting major cancer antigens and genes, and with, you know, with the desire to create a new product we can go from a concept to a new product in about three or four months. You know, in the human situation, we'll be looking at HER2-driven diseases that are well known, like breast cancer, as well as gastric and esophageal cancer, and potentially some other diseases that have HER2 driving the proliferation of the malignancy, so, it's not really just a one-disease thing. In addition, human osteosarcoma, although a small disease, is something of a great deal of interest to pediatric oncologists as well, particularly on the strength of the data that Nikki has generated. So, I think really, in this situation, dogs can be man's best friend, and man can be dog's best friend, and we'll all get along well together.

Dan O'Connor: And David, one other, one other quick point is Steven, you know, we definitely appreciate very much that Aratana recognizes the versatility of our platform.

David Moskowitz: Well again, thanks for taking my question, and thanks Aratana, for pedicaid and pedicare, the two new terms for me, I love it, thank you.

Operator: Thank you, and the next question is a follow up from Douglas Tsou with Barclays.

Douglas Tsao: Hello, good morning. Steven, obviously, you know, stepping away from the deal announced this morning, obviously the pace of business development on the part of Aratana over the last, you know, 13 months has been really remarkable, you know, your sort of pipeline has gone from I think it was three assets, you know, at the beginning of 2013, to today where you're looking at probably over 20 if we added them all up. You know, just curious in terms of your perspective, you know, how much bandwidth can your organization take on, and at what point, you know, will things potentially slow down; or do you think that you can continue, you know, you'll continue to seek out new opportunities and that, you know, given where your financial position today, you can sort of take those on given the sort of attractive economics.

Steven St. Peter: Yeah, so thanks, Doug. You know, it has been a remarkable pace, and you know, we have confidence in this business plan and we're aggressively pursuing it, and we've fortunately benefited from the support of the investor community who's allowed us to really pursue that very aggressive vision. You know, when we came out of the box after IPO, we bought our two largest competitors, which I mentioned earlier, to give us footprint in biologics, you know, as well as the existing small molecule, and then we bought Okapi to give us European presence, because we think that scale of addressing 60 percent of the market was crucial. The, you know, in our recent secondary, we communicated, and I'll affirm that today, from a, you know, we're done with acquisitions. We believe that, you know, that the acquisitions, you know, we, we've done the acquisitions that we need to do to, you know, to create the platform for us; and now we've funded those acquisitions with our secondary; but we also said, you know, that we would continue to in-license products, and this is an example of that, because I think rather than buying hardware for us with the now critical mass team in place, and you know, the financial wherewithal we have, it's about software, not hardware, and it's about products and collaboration and in-licensing - things that we did, you know, a year ago when we partnered with Pacira to get their liposomal depobupivacaine product, and we did a couple of acquisitions and now we're back to doing, you know, to doing partnerships and so, you know, if we can do deals like this - this for us is great. And with respect to our current portfolio, Doug, I mean, we recently gave guidance in terms of a \$25 - 30 million development spend for 2014, we you know, we affirm that, that's still what we're doing. You know, we have the ability now to manage the portfolio, and really to rationalize the portfolio based on where the big value is and building a portfolio that's very synergistic. So for instance, this asset fits ver

And so it really gives us the flexibility to, you know, in some cases, develop and commercialize all the products ourselves, but in other case rationalize the portfolio and work with strategic partners where it makes sense to do a partnering deal to help, you know, co-market or commercialize a product. So, you know, we really achieved the objective we set out to achieve, which is build a portfolio, and so we'll continue to add to that portfolio, that really rationalize the portfolio based on, you know, just the criteria around what's the most attractive and, and the highest return on invested capital for our investors; and very few companies in biotechnology have that luxury, 'cause they're usually dependent on one or two programs that consume all of the capital that they have, and you know, you can't shorten or reduce the number of patients in a phase three human trial - that never works for anybody, so you really can't manage your capital. We can manage our capital extremely well, both on the development side, but also on the commercial side because while we will have a direct sales organization, we will be partnering with distributors who have, you know, the three large distributors have over a thousand reps - so there are ways you can, you know, on the human side, you've got to do a national launch, because you've got to cover payers and retail pharmacies; we don't have to do that. So, there's a lot of different ways we can manage a portfolio this large and continue to add to it.

Douglas Tsao: Okay, great, thank you very much for that.

Operator: Thank you. And this concludes our question and answer session. At this time I would like to turn the callback over to Dan O'Connor for any closing remarks.

Dan O'Connor: Great, thanks. Thanks so much, and Steven, thank you. In closing, I'd like to thank the entire Aratana team. Advaxis is excited to be working with Aratana to bring our immunotherapy to the market for companion animals. Pet Therapeutic market opportunity is tremendous, and Aratana now add access to exploit that opportunity with certain of Advaxis's immunotherapy product candidates. We look forward to building a long, mutually beneficial relationship that will generate revenue for Advaxis, and value for our shareholders, as we continue to drive our human drug development forward. Thanks very much and have a great day.

Operator: Thank you. This conference is now concluded. Thank you for attending today's presentation, you may now disconnect. Have a nice day.