Zacks Small-Cap Research

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Advaxis Inc (ADXS-OTC)

ADXS: Unique immunotherapy platform technology with middle stage pipeline—maintaining an Outperform rating

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	04/07/2011
Current Price (12/12/11)	$0.16
12-month Target Price	**$0.50**

OUTLOOK

Advaxis is a Listeria based immunotherapy company focused on the development of immunotherapeutics for cancer treatment. We are optimistic about the Company's unique Listeria platform technology which has advantages over its peers. The Company's lead drug candidate ADXS11-001 is in Phase II clinical trials for the treatment of cervical cancer and cervical dysplasia. Another Phase II trial will be initiated for the treatment of head and neck cancer soon. Other pipeline candidates target breast, brain and prostate cancer. We believe Advaxis is heading in the right direction and we rate its shares Outperform.

SUMMARY DATA

52-Week High	**$0.25**
52-Week Low	**$0.10**
One-Year Return (%)	**-37.84**
Beta	**0.17**
Average Daily Volume (sh)	**493,748**
Shares Outstanding (mil)	**240**
Market Capitalization ($mil)	**$36**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**1**
Insider Ownership (%)	**13.4**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2011 Estimate	**N/A**
P/E using 2012 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**N/A**
Industry	**Med Products**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Jan)	Q2 (Apr)	Q3 (Jul)	Q4 (Oct)	Year (Oct)
2010	0.00 A	0.09 A	0.18 A	0.24 A	0.51A
2011	0.00 A	0.00 A	0.00 A	0.00 E	0.00 E
2012					0.00 E
2013					1.50 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Jan)	Q2 (Apr)	Q3 (Jul)	Q4 (Oct)	Year (Oct)
2010	-$0.03 A	-$0.03 A	-$0.01 A	-$0.00 A	-$0.06 A
2011	-$0.02 A	-$0.02 A	-$0.02 A	-$0.01 E	-$0.07 E
2012					-$0.05 E
2013					-$0.04 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW

Advaxis Completes Pre-IND Meeting for ADXS-HER2

Advaxis (ADXS) completed a pre-IND (Investigational New Drug) meeting with the FDA on November 22, 2011 to discuss the development plan for ADXS-HER2, an immunotherapy for the treatment of HER2 expressing cancers. The FDA addressed the Company's questions and provided guidance on the requirements to file an IND to initiate clinical trials. This IND is expected to be submitted in the first half of 2012.

HER2 (human epidermal growth factor receptor 2) is a gene which is over expressed in a percentage of certain types of cancers such as breast, stomach, bladder, pancreatic, brain, and ovarian.

ADXS- HER2 immunotherapy is the third Lm-LLO agent Advaxis is advancing to the clinic. ADXS-HER2 uses a proprietary chimeric form of the HER2 antigen (cHER2) that gives it the potential to overcome "escape mutations" in cancer, and has shown encouraging results in mouse models for HER2 positive **breast cancer** and preliminary data in brain cancer.

Advaxis Licenses Novel Antigen for Severe Breast Cancer and Other Tumor Types

On November 15, 2011, Advaxis (ADXS) exclusively licensed the use of antigen **ISG15** in Advaxis' Lm-LLO based immunotherapies from the University of Pennsylvania. This intellectual property resulted from research conducted in Dr. Yvonne Paterson's laboratory that demonstrated ISG15 was an effective immunological target for the treatment of breast cancer in animal models.

ISG15 is a novel protein associated with numerous cancers. Recently published data demonstrate that Advaxis' Lm-LLO immunotherapy reduced primary and metastatic breast tumors in an animal model when directed against ISG15. Therefore, targeting ISG15 may represent a new therapeutic approach suitable for a population of patients with advanced breast cancer for whom few approved treatments currently exist.

The research conducted by Dr. Paterson and colleagues, as well as research conducted at other institutions, suggests that ISG15 may have utility in treating other tumor types as well.

With the acquisition of ISG15, Advaxis' first proprietary antigen, Advaxis has further expanded its intellectual property assets and boosted its pipeline. This will help to sustain the long term growth of the Company in our view.

Balance Sheet has been Boosted through Additional Financing

On October 28, 2011, Advaxis (ADXS) entered into a definitive Convertible Notes Purchase Agreement for the purchase of the aggregate principal value of approximately $2.3 million of Convertible Promissory Notes for an aggregate purchase price of approximately $2.0 million. Investors include certain accredited investors as well as the CEO and the CFO of the Company.

The Notes purchased in the offering were paid for in cash or, with respect to Notes acquired by Advaxis Chairman/CEO Thomas A. Moore, in exchange for the cancellation of $400,000 of outstanding indebtedness owed by the Company.

On May 9, 2011, Advaxis Inc. (ADXS) announced that it has entered into a definitive convertible notes purchase agreement with certain accredited investors, for the purchase of the aggregate principal value of approximately $7.1 million of convertible promissory notes for an aggregate purchase price of approximately $6.0 million.

Advaxis will use the funds to support its operations and its Phase II clinical trials in cervical cancer and cervical dysplasia through initial data reporting. Advaxis also will use the funds to finish GMP manufacture of the prostate and breast cancer versions of its novel immunotherapeutic platform technology.

As of July 31, 2011, Advaxis had $1.8 million in cash.

Advaxis Reports 2011 Fiscal Third Quarter Financial Results

On September 12, 2011, Advaxis reported fiscal third quarter financial results ended July 31, 2011.

The Company did not record any revenue for the three months ended July 31, 2011. For the same period a year ago, revenue increased by approximately $177,000, representing grant revenue.

Research and development expenses increased by approximately $1,111,000 to approximately $1,959,000 for the three months ended July 31, 2011 as compared with approximately $848,000 for the same period a year ago principally attributable to clinical trial expenses increasing significantly resulting from the continuation of clinical trials in the United States and India, which were initiated during the first fiscal quarter of 2010. In addition, overall compensation expense was higher in the current period resulting from additional employees, increased stock-based compensation and increases in salaries and bonus.

General and administrative expenses increased by approximately $509,000 or 45%, to approximately $1,638,000 for the three months ended July 31, 2011 as compared with approximately $1,129,000 for the same period a year ago. This was the result of higher legal, professional and other consulting fees in the current period as compared with the same period a year ago primarily due to the sale of convertible debt instruments.

For the three months ended July 31, 2011, interest expense increased to approximately $1,770,000 from approximately $316,000 primarily resulting from the issuance of approximately $7.1 million of convertible promissory notes in May 2011. Interest expense includes the pro-ration of the original issue discount (approximately $233,000) and the amortization of fair values for both the embedded derivatives (approximately $833,000) and the warrants (approximately $924,000) from the May 2011 sale of convertible promissory notes.

For the three months ended July 31, 2011, the Company recorded income from the change in fair value of the common stock warrant liability and embedded derivative liability of approximately $9.1million compared with income of approximately $4.1 million in the same period a year ago. Decreases in the underlying stock price (and therefore decreases in the corresponding warrant liability and embedded derivative liability), over both three month periods, resulted in income being recorded by the Company.

Adjusted non-GAAP net loss was $5.6 million or $0.02 per share.

Pipeline Updates

Cervical Intraepithelial Neoplasia (CIN):

The Company announced on July 11, 2011 that it has completed enrollment of the first 40 subject cohort in the dose-ranging **Phase II** study of ADXS-HPV, an immunotherapy for Cervical Intraepithelial Neoplasia (CIN).

The ADXS-HPV CIN study is a randomized, single blind, placebo controlled Phase II dose-ranging study designed to assess the safety and efficacy in up to 3 different dose cohorts. The six-month follow-up

evaluation for this low dose cohort will be completed by January, 2012. The mid-dose leg will begin recruitment immediately. The Company's plan is to release the low dose results by the end of 2011.

In order to accelerate enrollment in mid dose leg, the Company revised protocol for the enrollment of the next 40 subject "mid strength" dose cohort, which has been approved by the FDA. The revised protocol eliminates a staggered dosing design that required two pauses in recruitment to evaluate the safety of all three doses in two successive small groups of patients. The pauses consumed about 5 months in the recently completed low dose cohort that took about 14 months to complete. Therefore, the protocol change could accelerate enrollment in mid dose leg by up to 5 months.

Prostate Cancer

Advaxis completed a pre-IND meeting with the FDA on August 10 to discuss the development plan for ADXS-PSA, a construct for the treatment of prostate cancer. The FDA addressed the Company's questions and provided guidance on the requirements to file an IND to initiate clinical trials.

Based on FDA input, the planned toxicology studies will be completed on schedule for a filing by year end. Once an **IND** is filed, FDA has 30 days to comment before the Company can begin Phase I trials

Canine Osteosarcoma

On July 7, 2011, Advaxis announced that the first dog has entered a dose-ranging in canine osteosarcoma at the University of Pennsylvania, School of Veterinary Medicine.

In 2010, Advaxis contracted with the University of Pennsylvania School of Veterinary Medicine to conduct a canine clinical program to determine the safety and efficacy of ADXS-HER2 in osteosarcoma. Positive results may lead to research in humans, as well.

The study will be under the direction of Dr. Nicola Mason, an assistant professor at the University of Pennsylvania School of Veterinary Medicine. Only dogs with a histological diagnosis of osteosarcoma and evidence of expression of HER2/neu by malignant cells will be eligible for enrollment.
All dogs will receive 4 weeks of carboplatin therapy. Four weeks after the last carboplatin dose, dogs will receive ADXS-HER2 once every three weeks for a total of 3 doses. Group 1 (3 dogs) will receive 1x108 CFU per dose, Group 2 (3 dogs) will each receive 5x108 CFU per dose and Group 3 (3 dogs) will receive 1x109 CFU per dose. Additional dogs may be added to a Group to gather more data should a potentially dose limiting toxicities, be observed. Therefore 9-18 dogs may be treated in the initial study.

Collaboration With Wistar Institute Explores New Opportunity

On April 14, 2011, Advaxis announced that it has entered into a research collaboration with the laboratory of Ellen Puré, Ph.D., professor/associate vice president for Academic Affairs at the Wistar Institute.

Dr. Puré's research defines the role of fibroblast activation protein (**FAP**) in cancer, and she has demonstrated that genetically deleting or therapeutically targeting FAP significantly reduces tumor growth in mice. FAP is over-expressed in the stroma of tumors. The stroma is the structural tissue matrix in which tumor cells grow, and part of the stroma are fibroblast cells. Fibroblasts are associated with cancer in all stages of development, since in order for tumors to grow they need to stimulate the growth of the stroma to accommodate the growth of new cancer cells within this matrix. By deactivating FAP in mouse models of lung and colon cancer, the laboratory of Dr. Puré has generated an understanding of how FAP promotes tumor growth. FAP inactivation disrupts the organization of the collagen fibers in the matrix which are critical for cell to cell communication, cell-matrix interactions and development of new blood vessels that feed tumors. The study provides proof of principle that targeting and modifying the tumor microenvironment may be an effective approach to treating a variety of solid tumors.

Advaxis will use these mouse models to explore the potential of FAP as a target for immune attack and as the basis for the development of a live attenuated Listeria vaccine. Advaxis plans to use its proprietary Lm-LLO technology to create and test an attenuated Listeria vaccine to FAP, both as a single antigen vaccine, and possibly as a dual antigen vaccine in combination with another tumor target, to see which approach is the most effective. The Company's objective is to bring an FAP vaccine to the clinic as soon as possible.

KEY POINTS

- We maintain our Outperform rating for Advaxis (ADXS) and reiterate our twelve-month price target is $0.50.

- Advaxis is a Listeria-based immunotherapy company focused on the development of therapeutic vaccines for the treatment of various cancers. The Listeria platform technology is unique and holds advantages over its peers in three ways.

    - Advaxis' Listeria-based cancer vaccine can deliver bioengineered cancer antigen fused with a unique, proprietary strong adjuvant LLO which elicits both innate and adaptive immune systems in the body to fight cancer. The immune response elicited by Advaxis' cancer vaccines has been the most comprehensive and robust so far in the industry.

    - Advaxis' cancer vaccines can reduce the amount of regulatory T cells and myeloid suppressor cells which help protect tumors from attacking by cytotoxic T cells.

    - Another distinctive feature of Advaxis' cancer vaccines is their ability to change the ratio between killer T-cells and regulatory T cells (the Kill Ratio) inside the tumor from 1:1.3 to 22.7:1.

- Based on its proprietary Listeria technology, Advaxis has established a pipeline targeting various cancer indications. The Company's lead candidate is ADXS11-001. Pre-clinical and Phase I clinical trials have demonstrated that ADXS11-001 is well tolerated and has shown impressive efficacy in cervical cancer patients.

- ADXS11-001 is currently under two Phase II clinical trials for the treatment of cervical cancer and cervical dysplasia, respectively. Another two Phase II trials for the treatment of cervical cancer and head and neck cancer are planned to initiate in 4Q2011.

- Early stage candidates include ADXS31-142 for prostate cancer and ADXS31-146 for breast and brain cancer as well as canine osteosarcoma. Phase I trials for these two candidates will be conducted if funds are available.

- We believe Advaxis' Listeria technology is a viable drug delivery system which targets the rather large cancer market. The Company's shares are undervalued in our view. Risk is higher though at this point, return should be also high if any progress can be made in advancing its pipeline.

- Risks include cash burn concern, early to middle stage development risk, and over-the-counter market trading.

OVERVIEW

Advaxis (ADXS) is a development stage biotechnology company focused on the research, development and commercialization of safe and effective **therapeutic cancer vaccines** that utilize multiple mechanisms of immunity.

The Company is developing a live, attenuated **Listeria vaccine technology** under license from the University of Pennsylvania which secretes a protein sequence containing a tumor-specific antigen. This vaccine technology is capable of stimulating the body's immune system to process and recognize the antigen as if it were foreign, generating an immune response able to attack the cancer. This is a broadly enabling platform technology that can be applied to the treatment of many types of cancers, infectious diseases and auto-immune disorders.

This technology involves the creation of genetically engineered Listeria that stimulates the immune system to induce antigen-specific anti-tumor immune response involving both innate and adaptive arms of the immune system. In addition, this technology facilitates the immune response by altering tumors to make them more susceptible to immune attack, and increasing the number and maturation of development of specific cells that underlie a strong therapeutic immune response.

Advaxis has focused its initial development efforts upon therapeutic cancer vaccines targeting cervical cancer, its predecessor condition, cervical intraepithelial neoplasia (CIN), head and neck cancer, breast cancer, prostate cancer, and other cancers. The Company's lead products in development are as follows:

Figure 1: Advaxis' development pipeline

Product	Indication	Stage
ADXS11-001	Cervical Intraepithelial Neoplasia (CIN)	**Phase II** Company sponsored study, commenced in April 2010 (with patient dosing commencing in May 2010).
	Cervical Cancer	**Phase II** Company sponsored study initiated in November 2010 in India. 110 Patients with advanced cervical cancer.
	Cervical Cancer	**Phase II** The Gynecologic Oncology Group of the National Cancer Institute has agreed to conduct a study which is expected to begin in 4Q2011.
	Head & Neck Cancer	**Phase II** The Cancer Research UK (CRUK) is funding a study of up to 45 patients at 3 UK facilities that is expected to commence in 4Q2011.
ADXS31-142	Prostate Cancer	**Phase I** Company sponsored (expected to file IND by end of 2011).
ADXS31-164	Breast /Brain Cancer	**Phase I** Company sponsored (1H2012).
ADXS31-164	Canine Osteosarcoma	**Phase 1** Company sponsored (Initiated July 2011).

Source: company filings/ website and Zacks Investment Research

Advaxis is the survivor entity of a reverse merger between Advaxis and a shell company Great Expectations, Inc. in November 2004. On July 28, 2005, Advaxis' shares began trading on the Over-The-Counter Bulletin Board (OTC: BB) under the ticker symbol ADXS.

The Company is headquartered in Princeton, NJ.

INVESTMENT THESES

The Unique Listeria Platform Technology

Advaxis develops immunotherapeutics using a live but attenuated Listeria as the delivery vector in targeted treatment of cancers (cancer vaccines). This unique, proprietary platform technology is based upon the work of Yvonne Paterson, Ph.D., Professor of Microbiology at the University of Pennsylvania.

Listeria monocytogenes bacterium **(Lm**, **Listeria**) is a ubiquitous environmental pathogen found in the soil, on leafy vegetables, in meat, and in dairy products. Typical exposure to Lm does not result in disease. Listeria is not laterally transmissible and is only pathogenic when ingested. Globally, listeriosis is a rare disease and its prevalence has declined wherever food control measures have been implemented.

Advaxis' Listeria technology uses a patented delivery system to target various cancers using attenuated, live *Listeria* as vectors to deliver a **tumor-associated antigen** fused to the protein **listeriolysin-O (LLO),** which elicits a powerful and comprehensive immune response.

Attenuation of Lm by deletion of multiple virulent genes in the bacteria greatly increases safety of the bacteria, while retaining their potent immunogenicity. Listeria vaccines are highly attenuated, which means they are much less pathogenic. Advaxis vaccines are between 10,000 and 100,000 times weaker than wild type Listeria. The attenuated Listeria will not cause disease themselves.

In addition to attenuation, Advaxis further bioengineered Listeria based on the details of Listeria's intracellular activity. Specifically, Advaxis fuse a tumor antigen to a virulence factor listeriolysin (LLO) within the Listeria bacterium. The combination of the tumor antigen and LLO generates a strong immune response attacking the cancer. All distinctive features of Advaxis' vaccines are derived from the fusion protein.

In order to understand why Advaxis' Listeria platform technology is unique, we need to understand the mechanisms of action and the advantages of the technology first.

Mechanism of Action

When Listeria enters the body, it is seen as foreign by the antigen presenting cells and ingested into cellular compartments called phagolysosomes, whose destructive enzymes kill most of the bacteria. A certain percentage of these bacteria, however, are able to break out of the phagolysosomes and enter into the cytoplasm of the cell, where they are relatively safe from the immune system. The bacteria multiply in the cell, and the Listeria is able to move to its cell surface so it can push into neighboring cells and spread without entering the extracellular space for destruction. Antigens produced by these bacteria enter the Class I pathway and directly stimulate a cytotoxic T cell response.

It is the details of Listeria intracellular activity that are important for understanding Advaxis technology. Inside the lysosome, Listeria produces virulence factor **listeriolysin-O (LLO)**, a protein that creates a hole in the membrane of the lysosome that allows the bacteria to escape into the cytoplasm. Once in the cytoplasm, however, LLO is also capable of creating a hole in the outer cell membrane. This would destroy the host cell. To prevent this, the body has evolved a mechanism for recognizing a specific amino acid sequence in LLO called **PEST sequence** (for the predominant amino acids it contains). When a PEST sequence is detected, it is used by normal cells to digest the protein in the cytoplasm. This PEST sequence serves as a routing tag that tells the cells to route the LLO in the cytoplasm to the proteosome for digestion, which terminates its action and provides fragments that then go to the endoplasmic reticulum, where it is processed just like a protein antigen in the endogenous pathway to generate MHC-1 complexes.

This mechanism is used by Listeria to its benefit, because the actions of LLO enable the bacteria to avoid digestion in the lysosome and escape to the cytosol where they can multiply and spread and then be neutralized so that it does not kill the host cell. Advaxis is using a technology that co-opts this mechanism by creating a protein that is comprised of the cancer antigen fused to a non-hemolytic portion of the LLO molecule that contains the PEST sequence. This serves to route the molecule for accelerated proteolytic degradation **which accelerates both the rate of antigen breakdown and the amount of antigen fragments** available for incorporation in to MHC-1 complexes; thus increasing the stimulus to activate cytotoxic T cells against a tumor-specific antigen. Moreover, LLO is a very strong **adjuvant**, which means it is a strong stimulator of innate immunity.

Other mechanisms that Advaxis vaccines employ include Listeria's ability to increase the synthesis of myeloid cells such as APCs and macrophages, and to stimulate the maturation of immature myeloid cells to increase the number of available activated immune cells that underlie a cancer- killing response. Immature myeloid cells actually inhibit the immune system and Listeria removes this inhibition within the actual tumor. Also, Listeria and LLO both stimulate the synthesis, release, and expression of various chemicals which stimulate a therapeutic immune response. These chemicals are called cytokines, chemokines and co-stimulatory molecules. By doing this, not only are immune cells activated to kill cancers and clear them from the body, but local environments within tumors are created that support and facilitate a therapeutic response.

Finally, in a manner that appears to be unique to Advaxis' live attenuated Listeria vaccines: they can reduce the number and function of immunosuppressive cells that tumors recruit to protect them from therapeutic immune attack. Over the past few years it has become known that the reason many previous immunologic cancer treatments have failed is that although they were able to strongly activate the immune system, they were rendered ineffective by endogenous sources of immune inhibition within the tumors themselves. Advaxis has demonstrated that its Listeria vaccines have the ability to reduce the number of regulatory T cells and Myeloid Derived Suppressor Cells (MDSC). This renders tumors susceptible to immune attack. The ability to reduce the effect of immunosuppressive cells within tumors is currently under clinical investigation by other companies and is believed to be a significant mechanism of achieving a therapeutic response.

Advantages of Listeria Based Vaccines

Listeria based vaccines are unique for many reasons.

Unlike viral vectors, DNA or peptide antigens or other vaccines, Listeria vaccines stimulate every immune pathway simultaneously (both innate immune system and adaptive immune system), and in an integrated manner. It has long been recognized that cytotoxic T lymphocytes (CTL) are the elements of the immune system that kill and clear cancer cells. The amplified CTL response to Listeria vaccines are one of the strongest stimulators of CTL yet developed, but just as important is the ability Advaxis vaccines have to create a local tumor environment in which these cells can be effective. This efficacy likely results in part from the fusion of LLO to the secreted tumor antigen since many studies have shown that LLO is a very strong source of immune stimulation independent of Listeria. By fusing a molecule with strong adjuvant properties to a tumor antigen, and then having it synthesized and secreted by live bacteria directly into the cytoplasm of Antigen Presenting Cells, vascular endothelium and other relevant tissues, an unusually powerful and complete immune response is generated.

Recently Advaxis has shown that Lm -LLO vaccines can cause epitope spreading. This means that these vaccines can stimulate the immune system to respond to more antigens than the one they are designed to attack. This happens when tumor cells are killed by the immune system in response to the administered vaccine and portions of those killed cells are then recognized by the immune system and they too become targets of an immune attack. This broadens the immune attack and results in a more therapeutic response.

Importantly, Advaxis' live attenuated Listeria vaccines do not stimulate antibody formation, which is important because other types of cancer vaccines such as those that use viruses develop antibody responses which inactivate them and prevent them being used repetitively in a vaccine regimen. These types of vaccines are inactivated by antibody responses before they can effectively deliver their immune payload which prevents them from stimulating a therapeutic response. Advaxis' vaccines can be used effectively in a multidose vaccine regimen as they are not inactivated by antibody responses.

Perhaps the most distinctive feature of Listeria based vaccines is their ability to alter the tumor microenvironment. It is now known that stimulating the immune system is not sufficient by itself to treat cancer because tumors have the ability to turn off activated immune cells once they get into tumor tissue. Tumors create within themselves this immune privileged space, which Listeria vaccines can reverse. Listeria vaccines achieve this by increasing the amount of cytotoxic T cells and simultaneously decreasing the amount of regulatory T cells, myeloid derived suppressor cells within the tumor cells. This enables the strongly activated immune system that Listeria stimulates to be effective within tumors, something other technologies cannot do.

Figure 2: Increasing the "Kill Ratio" Inside the Tumor

Vaccine	Killer T Cells (%)	Regulatory T Cells (%)	Killer Ratio
Listeria E7 (-LLO)	9.4	11.8	**1.0 : 1.3**
ADXS11-001 (+LLO)	36.8	1.7	**22.7 : 1.0**

Source: Company presentation

Advaxis' live attenuated Listeria vaccines also have the ability to modify the function of vascular endothelial cells in a way that facilitates the trafficking of activated immune cells out of the blood and into the tumor, where they are therapeutically effective. One property of cancer is the modification of vascular cells to prevent activated immune cells from transiting into the tumor. Listeria vaccines appear to overcome this source of anti-tumor inhibition.

Thus, what makes Advaxis live, attenuated Listeria vaccines so effective are a combination of effects that stimulate multiple arms of the immune system simultaneously in a manner that generates an integrated physiologic response conducive to the killing and clearing of tumor cells.

A Robust Pipeline Targets Various Cancer Indications

Advaxis uses genetically engineered and highly attenuated Listeria as a therapeutic agent. The Company starts with an attenuated strain of Listeria, and then adds to this bacterium multiple copies of a plasmid that encodes a fusion protein sequence that includes a fragment of the LLO molecule joined to the tumor antigen of interest. This protein is secreted by the Listeria inside the antigen presenting cells (APC), and other cells that Listeria infects which then results in the immune response. Advaxis can use different tumor, infectious disease, or other antigens in this system. By varying the antigen, different therapeutic agents are created. Listeria vaccines are stable, may be stored at room temperature.

ADXS11-001 targets multiple cancers

The Company's lead agent is **ADXS11-001** (Lm-LLO-E7) which is a recombinant live-attenuated Lm that secretes the antigen HPV-16 E7 fused to LLO. The synergies achieved by the combination of antigen E7 and adjuvant LLO is two fold: increasing amount of cytotoxic T cells, attacking the tumor and reducing amount of regulatory T cells and myeloid-derived suppressor cells (MDSC) protecting the tumor. In animal tests, ADXS11-001 has consistently eliminated pre-existing tumors in 75% of animals and in 50%

of animals genetically engineered to contract the cancer. Among animals whose tumors have been eliminated, cancer can not be successfully reintroduced.

The antigen HPV-16E7 is correlated with many cancers, and the Company is initially targeting cervical cancer, cervical intraepithelial neoplasia (CIN), a pre-cervical cancer, and head and neck cancer.

ADXS11-001 for Cervical Cancer

Advaxis has completed a **Phase I** clinical trial of ADXS11-001 for cervical cancer. ADXS11-001 targets the HPV onco-protein E7. HPV is recognized as the cause of cervix cancer and E7 is one of the HPV proteins believed to be responsible.

In the Phase I clinical trial, doses of $1x10^9$, $3.3x10^9$ or $1x10^{10}$ cfu were administered to three groups of 5 women with advanced cervical cancer who had failed prior therapy including radiation and chemotherapy. In such cases no therapy has been found to be effective and the historical Gynecological Oncology Group (GOG) median survival once disease progression resumes is typically 6 months or less, depending upon the treatment given. One-year survival for these patients historically is approximately 5%.

ADXS11-001 was well tolerated in the Phase I trial with mild to moderate fever, chills, nausea and vomiting. Symptoms were resolved with non-steroid anti-inflammatory drugs and anti-histamines (no antibiotics were needed). Dosing ceiling was established.

In 15 patients treated with ADXS11-001, 7 achieved stable status, 3 achieved tumor reduction and 1 achieved partial response. The Phase I trial of ADXS11-001 was intended to assess safety, and was not powered for efficacy, and so no conclusions can be made based upon the small number of patients treated. However, impressive preliminary efficacy data were observed. In this trial the median survival was 347 days and the 1 year survival was 53%.

Figure 3: Phase I trial survival data for cervical cancer patients

	12-Month	Median	Days alive
GOG Historical Controls	5%	180 days	**---**
ADXS11-001	53%	347 days	1,000+

Source: Company presentation

We think the Phase I trial results are remarkable compared to historical data though it's a small population trial. Based on the positive Phase I results, Advaxis initiated a **Phase II** clinical trail of ADXS11-001 in November 2010 **in India** for the treatment of advanced cervical cancer patients. About 110 patients will be enrolled in this Phase II trial.

Because of the progressive and rapidly fatal nature of cervix cancer in women for whom cytotoxic treatment has failed, the design of this trial allows for a rapid appraisal of overall survival. Historically, when given the most effective regimen tested to date, these patients have a median survival of approximately 6 months and a 1 year survival of 5%, and so by assessing survival in real time it will be possible to assess the effect of ADXS11-001 on survival versus these historical values before the end of the trial.

This Phase II trial differs from the Phase I trial in this patient population in three significant ways. First, unlike Phase I in which two doses of ADXS11-001 was administered, this Phase II will assess the more

therapeutic regimen of three doses. Second, this randomized trial compares ADXS11-001 alone to ADXS11-001 given in a combined regimen with platinum based chemotherapy. This is very important, as the scientific literature indicates that combined immuno- and chemo-therapy regimens may be more effective than single agent regimens, and Advaxis has generated some anecdotal data in support of this idea in the Phase I trial. Third, the ADXS11-001 regimen has been reduced from a 30 minute 250 ml infusion followed by I.V. and oral antibiotics over an 11 day period to an 80 ml 15 minute infusion followed by a seven-day oral course of antibiotic, which is easier to administer and thus more "clinic friendly"

Patients will be randomly assigned to receive either 3 administrations of ADXS11-001 or a single dose of the immunotherapy, followed by **cisplatin** treatment, followed by a three course regimen of ADXS11-001. Various clinical and immunologic measures will be taken, and survival will be followed for the life of the patient.

Top line results of this India Phase II trial will be available in fourth quarter of 2011.

Another **Phase II** trial of ADXS11-001 for the treatment of advanced cervical cancer patients will start in the 4Q 2011 by the Gynecologic Oncology Group (GOG) of the National Cancer Institute (NCI). About 63 patients will be enrolled in this trial. Advaxis is responsible for covering the costs of translational research and has agreed to pay a total of $8,003 per patient, with the bulk of the costs of this study underwritten by NCI.

ADXS11-001 for Cervical Intraepithelial Neoplasia

Cervical intraepithelial neoplasia (**CIN)**, also known as **cervical dysplasia** or cervical interstitial neoplasia is the abnormal appearance of cells on the surface of the cervix when they are looked at underneath a microscope. Although this is not cancer, it is considered a precancerous condition.

Like cervical cancer, almost all cases of cervical dysplasia are caused by human papilloma virus (HPV). Therefore, it's a natural logic that ADXS11-001 can also target CIN.

In April 2010, Advaxis initiated a multicenter, randomized, single blind, placebo-controlled, **Phase II** clinical trial of ADXS11-001 for the treatment of cervical intraepithelial neoplasia (CIN). The study is designed to assess the safety and efficacy of ADXS11-001 for the treatment of CIN grade 2/3, which is late stage cervical dysplasia that requires surgery to prevent invasive cancer. Numoda Corporation is Advaxis' strategic partner in the conduction and execution of this trial.

Dosing of patients began in late May 2010, and total of 120 patients will be enrolled in this trial.

CIN is diagnosed in 450,000 American women annually. Progressive CIN is currently treated with surgery to prevent cancer from occurring. However, this treatment is associated with a number of problems, which include the development of an "incompetent cervix" i.e., a condition that prevents women from carrying a baby to full term. The typical CIN patient is a woman between 25 and 45 years of age. Although surgery is a viable short-term solution for the condition, it does not address the cause of the disease, which is a human papilloma virus (HPV) infection. Women who require surgery once may need it again. Current HPV vaccination products have not demonstrated effectiveness against active HPV infections.

ADXS11-001 for Head and Neck Cancer

The rationale of ADXS11-001 treatment for head and neck cancer is that HPV is linked to some head and neck cancers especially the cancer of oropharynx. ADXS11-001 specifically targets the antigen of HPV and could be an important treatment option for head and neck cancer patients.

The Cancer Research UK (CRUK) will initiate a **Phase II** clinical trial of ADXS11-001 for the treatment of patients with Head and Neck cancers in second quarter of this year. Total of 45 patients will be enrolled at three UK facilities. The purpose of this trial is to assess ADXS11-001's safety and efficacy in head and neck patients who have previously failed treatment with surgery, radiotherapy and chemotherapy – alone or in combination.

CRUK will fund this Phase II clinical trial and Advaxis will provide the vaccines.

Other Listeria vaccines

In addition to ADXS11-001 which specifically targets HPV antigen, Advaxis has also developed multiple Listeria constructs targeting different antigens.

ADXS31-142 specifically targets prostate specific antigen (PSA), which is the basis of the common blood test used to indicate the presence of **prostate cancer**. It is an antigen that is currently being used by many companies in the development of prostate specific therapies. A Listeria construct containing a PSA-LLO fusion protein has been developed, and has been shown to be stable and very effective in animal models of prostate cancer. ADXS31-142 may enter into clinic late this year.

ADXS31-164 targets Her2/Neu gene. Her/2-neu is over expressed in various cancers such as breast (40%), melanoma (30%), pancreatic (20%), ovarian (30%) & gastric (19%). The Company developed a novel vaccine based on an entirely new vaccine strain of Listeria that is more attenuated and more immunogenic than the strain currently in the clinic with ADXS11-001. By identifying and isolating the immunogenic portions of the multiple vaccines tested the Company was able to create a chimeric antigen comprised of these immunogenic epitopes and fuse it to LLO to create an extremely powerful vaccine.

Advaxis has shown in animal models that ADXS31-164 not only eliminates existing tumors, but also prevents metastases. This vaccine can treat brain tumors, and even prevented the occurrence of spontaneous tumors in a year long study of transgenic animals who have had tumor causing oncogenes inserted into their DNA, and who thus get tumors spontaneously.

The Company plans to initiate a **Phase I** clinical trial of ADXS31-164 for **breast cancer** and **brain cancer** when funding is available.

The Company has entered into a clinical trials agreement with the School of Veterinary Medicine at Penn to investigate the use of its compound ADXS31-164 for the treatment of osteosarcoma in dogs. This disease is the leading cancer killer of large dogs and is a model for the treatment of human osteosarcoma, the leading fatal bone cancer in adolescents. A **Phase I** clinical trial of ADXS31-164 for the treatment of **canine osteosarcoma** is planned.

Collaborations further Validates Technology and Pipeline Potential

On October 29, 2010, Advaxis and the Vaccine Section of **National Cancer Institute (NCI)** signed a Collaborative Research and Development Agreement (CRADA) for the development of live attenuated Listeria vaccines for the treatment of cancer. Advaxis will provide all live Listeria vaccines. NCI will use different in vitro and in vivo models to elucidate the effect of Advaxis live attenuated Listeria vaccines on many different types of immune cells, and will investigate the mechanisms by which live Listeria vaccines reduce cancer induced immune inhibition that protects tumors from immune attack. Advaxis and NCI will use the results of this work to enhance the anti-tumor effects of live Listeria vaccines as therapeutic agents for the treatment of cancer and as therapeutic immune adjuvants that alter the tumor milieu which will enable them to be used with other modalities of cancer treatment. The cost of the CRADA is $150,000 annually and the length of the agreement is three years.

On June 17, 2010, Advaxis and the Science and Technology Directorate division of **the Department of Homeland Security (DHS)** signed a cooperative research and development agreement (CRADA). The Science and Technology (S&T) Directorate is the primary research and development arm of the Department of Homeland Security. The S&T Directorate's mission is to improve homeland security by providing to customers state-of-the-art technology that helps them achieve their missions. S&T customers include the operating components of the Department, and state, local, tribal and territorial emergency responders and officials. The Directorate has three portfolios that address basic research through advanced technology development and transition - spanning six primary divisions that address critical homeland security needs.

The DHS will initially conduct a pilot proof-of-concept study in cattle investigating the safety of Advaxis Listeria constructs for use in animals. Oral and injection dosing will be tested.
At the front of **infectious diseases**, Advaxis entered into a structured collaboration with the laboratory of Dr. Tobias Kollmann at the **University of British Columbia** (UBC) to develop live attenuated Listeria vaccines for the treatment of infectious diseases and to develop new dosage forms of Listeria vaccines. The same immune-stimulating properties of Listeria cancer vaccines may also have application for the treatment of infectious disease. Dr. Kollmann is an immunologist and neonatal vaccinologist who has published extensively on the use of Listeria vaccines as potential therapeutic agents for the treatment of childhood diseases. Under the terms of this collaboration, Dr. Kollmann will use Advaxis' proprietary Listeria vaccine vectors for the development of novel infectious disease applications.

The above three collaborations add additional scientifically respected organizations to the existing cooperative research agreements. These agreements significantly expand the development of Advaxis technology at low or no cost. All these collaborations further validate Advaxis live attenuated Listeria technology and pipeline potential.

Market Opportunities for Advaxis

Advaxis is targeting the multi-billion dollar cancer market with its unique therapeutic cancer vaccines. With a combined market size of $47.7 billion, cancer is one of the largest, fastest growing markets in the pharmaceutical industry. Meanwhile, the market will continue to expand over the coming years. Forecast sales of the total oncology market are estimated at $65.2 billion in 2014.

Immunotherapy Represents a Brand New Treatment Regime for Cancers

Cancer treatment with therapeutics has made great progress in the past decade. **Chemotherapy** has long been the only option for oncologists to fight cancers. But the toxicities associated with chemotherapeutics have limited their use. While killing cancer cells, chemotherapeutic agents also kill healthy cells within the body making them highly toxic to humans. The situation changed when **targeted therapy** entered into the market a decade ago. Targeted therapeutic agents selectively kill cancer cells while leaving healthy cells unattacked. The combination of chemotherapy and targeted therapy has become the standard regime of cancer treatment currently.

However, the advent of targeted therapy has not solved the long existing, notorious problem of cancer treatment: relapse, or recurrence. The regenerative power of cancer has come to occupy the very center of cancer study. And Scientists and clinicians believe that **immunotherapy** could be the ultimate solution to cancer recurrence. Immunotherapy represents a brand new treatment regime for cancers. Unlike the current standard of care, therapeutic vaccines represent a paradigm shift in the treatment and chronic management of cancer due to the potential to positively affect survival in conjunction with minimal side-effect profiles. Cancer vaccines represent a long sought after, novel approach to combat existing cancer as well as the potential to prevent the formation of new tumors.

However, immunotherapy has not gained much attention in the past decade until recently when Dendreon's Provenge was approved by the FDA as the treatment of advanced prostate cancer in April 2010.

Dendreon's **Provenge** is the first cancer vaccine that got the FDA nod at the end of April, 2010 for the treatment of advanced, hormone-resistant prostate cancer. This is certainly good news for the whole class of therapeutic cancer vaccines including Advaxis' ADXS11-001 because Provenge approval set a clear regulatory path for other cancer vaccines.

Listeria Technology Holds Advantages over Provenge and Other Immunotherapies

The major challenge for making Provenge is **manufacturing/logistics problem**. Provenge is dendritic cell-based immunotherapy. It takes three steps to produce Provenge. First, the patient goes to a blood center for a leukapheresis procedure to collect the patient's own immune cells; Secondly, the isolated cells are sent to Dendreon's manufacturing facility to produce Provenge; Thirdly, the finished Provenge is shipped to an infusion center to treat the patient. The recommended course of therapy for Provenge is 3 complete doses within one month. Depending on the patient location and the location of Dendreon's manufacturing facility, the whole process from the cell collection to patient infusion could take up to 72 hours.

Advaxis' cancer vaccines are based on Listeria technology, which is totally different from the dendritic cell-based vaccines in terms of manufacturing/logistics although the ultimate goal of both regimes is to activate the immune system in the patient's own body to fight cancer. In addition to manufacturing/logistical advantage, Advaxis' Listeria-based cancer vaccine can deliver bioengineered cancer antigen fused with a unique, proprietary strong adjuvant LLO which elicits both innate and adaptive immune systems in the body to fight cancer. The immune response elicited by Advaxis' cancer vaccines has been the most comprehensive and robust so far in the industry. Further, Advaxis' cancer vaccines can reduce the amount of regulatory T cells and myeloid suppressor cells which help protect tumors from attacking by cytotoxic T cells. Another distinctive feature of Advaxis' cancer vaccines is its ability to change the ratio between killer T-cells and regulatory T cells (the Kill Ratio) inside the tumor from a 1:1.3 to a 22.7:1.

Market Opportunity for ADXS11-001

ADXS11-001 targets the HPV antigen and is indicated for the treatment of cervical cancer, cervical dysplasia and head and neck cancer.

Cervical cancer is usually a slow-growing cancer that may not have symptoms but can be found with regular Pap tests. Cervical cancer is almost always caused by human papilloma virus (HPV) infection. There were about 12, 200 new cases of cervical cancer in the US and 4,200 died of cervical cancer in 2010. Cervical cancer used to be the leading cause of cancer death for women in the United States. However, in the past 40 years, the number of cases of cervical cancer and the number of deaths from cervical cancer have decreased significantly. This decline largely is the result of many women getting regular Pap tests, which can find cervical precancer before it turns into cancer. Recent approval of Merck's Gardasil and GSK's Cervarix should have a positive impact on cervical cancer incidence in the coming years.

Both Gardasil and Cervarix are **prophylactic** cancer vaccines approved for the prevention of cervical cancer caused by HPV. Both vaccines target HPV strains and will help to reduce the incidence of cervical cancer in the future. Gardasil is directed against four HPV strains while Cervarix is directed against two. Neither of these agents has an approved indication for women who have a prior exposure to the HPV strains that they protect against, nor are women protected from other strains of HPV that the drugs do not treat.

We think the presence of these agents in the market does not eliminate the market for a therapeutic vaccine such as ADXS11-001 directed against invasive cervical cancer and CIN for a number of reasons:

- HPV is the most common sexually treated disease in the U.S., and since prior exposure to the virus renders these anti-viral agents ineffective they tend to be limited to younger women and do not offer protection for women who are already infected. The number of women who are already infected with HPV is estimated to be as much as (or more than) 25% of the female population of the U.S.

- There are approximately 10 high risk strains of HPV, but Gardasil and Cervarix only protect against the most common 2-4 strains. If a woman contracts a high risk HPV species that is not one of those, the drugs will not work.

- Women with HPV are typically infected for over twenty years or more before they manifest cervical cancer. Thus, the true prophylactic effect of Gardasil and Cervarix can only be inferred at this time. There currently exists a significant population of young woman who have not received these agents, or for whom they will not work, and who will manifest HPV related cervical disease for the next 40+ years. This population will continue to grow until such time as a significant percentage of women who have not been exposed to HPV are vaccinated; which is not likely to occur within the next decade or longer. We do not know at this time whether a significant number of women will be vaccinated to have an effect on the epidemiology of this disease.

- With the exception of the campaign to eradicate polio in which vaccination was mandatory for all school age children, vaccination is a difficult model to accomplish because it is virtually impossible to treat everyone in any given country, much less the entire world. This is especially true for cervical cancer, as the incentive for men to be vaccinated is small, and infected men keep the pathogen circulating in the population.

Therefore, we believe there will be a market for cervical cancer and CIN for the foreseeable future. The market opportunity is even bigger for ADXS11-001 when we add the head and neck market into cervical cancer/CIN market.

Strong Management Team and Advisors

Thomas A. Moore, *Chairman of the Board of Directors and CEO*
Mr. Moore has been with the Company since September 2006. He brings more than 25 years of experience in healthcare, executive management and business development. Some of his notable accomplishments include the $246 million sale of Nelson Communication to the Publicis Group and the development of Aleve and Actonel for Procter & Gamble (NYSE: PG) where he had a 23-year tenure. At P&G he served as president of the Healthcare Products Sector-Worldwide and group VP of the parent company. Mr. Moore holds a BA in History from Princeton University.

Mark J. Rosenblum, *Chief Financial Officer, Secretary and Senior VP*
Mr. Rosenblum joined the Company in January 2010. He brings to Advaxis over 25 years experience in accounting and financial leadership. Between 1985 and 2003 Mr. Rosenblum was employed by Wellman, Inc., (NYSE:WLM), a chemical manufacturing company, where he served in roles of increasing responsibility including chief accounting officer, VP and controller. Prior to Advaxis, he was the CFO of HemoBioTech, Inc., (OTCBB: HMBT) a biotechnology company primarily engaged in the commercialization of human blood substitute technology licensed from Texas Tech University. Mr. Rosenblum holds both Masters in Accountancy and a B.S. degree from the University of South Carolina and is a certified public accountant.

John Rothman, PhD, *Executive VP, Science & Operations*
Dr. Rothman has been with Advaxis since March 2005 and brings more than 30 years of clinical knowledge and expertise in the disciplines of infectious disease, gastroenterology, neurology, oncology and virology. Among his significant accomplishments are his work in the very first clinical trial of AIDS during his tenure at Schering-Plough Corporation and then Roche AG where he ran Roche's global data

collection, analysis and report writing. Dr. Rothman studied under Drs. Louis Ignarro (Nobel Prize; Medicine,'98) and Andrew Schally (Nobel Prize; Medicine,'77).

Robert Petit, PhD, *VP of Clinical Operations*
Dr. Petit joined Advaxis from Bristol Myers Squibb (BMY) where he was the U.S. Medical Strategy Lead for the Ipilimumab program, director of Medical Strategy for New Oncology Products, and director of Global Clinical Research. Prior to joining Bristol Myers-Squibb, Robert served as vice president of Clinical Development at MGI Pharma and also at Aesgen Inc. Dr. Petit has 23 years' experience in all medical and scientific aspects of pharmaceutical development. He has led programs in discovery, translational development and intellectual property development and has designed and conducted U.S. and international clinical evaluation programs from phase I to IV.

Yvonne Paterson, Ph.D., *Advisor*
Dr. Yvonne Paterson is a Professor in the Department of Microbiology, Associate Dean for Postdoctoral Research Training and Director of Biomedical Postdoctoral Programs at the University of Pennsylvania School Of Medicine. She is also a member of the University of Pennsylvania Cancer Center and the Center for AIDS Research. Dr. Paterson completed her B.Sc. and M.Sc. in Biochemistry at the University of Manchester, England. Additionally, she received her BA in Mathematics and Philosophy from the Australian National University and completed her Ph.D. in Biochemistry at Melbourne University in 1979. She continued her training as a Postdoctoral Fellow at Cornell University from 1979-82 and then became an Assistant Professor in the Department of Immunology at the Scripps Research Institute. She joined the faculty of the Microbiology Department at the University of Pennsylvania in 1988 and was promoted to full Professor in 1993.

Mark Einstein, M.D., *Advisor*
Dr. Einstein received his BS degree in Biology from the University of Miami, where he also received his MD with Research Distinction in Clinical Immunology. He also has an MS in Clinical Research Methods, which he received with Distinction. Dr. Einstein completed his residency in OB/GYN at Saint Barnabas Medical Center, and was a Galloway Fellow in Gynecologic Oncology at the Sloan-Kettering Cancer Center. Dr. Einstein has been at the Albert Einstein Cancer Center and Montefiore Medical Center since 1999, where he has been an attending physician, Assistant Professor of Gynecologic Oncology, and currently the Director of Clinical Research of the Division of Gynecologic Oncology at the Albert Einstein College of Medicine and Cancer Center, and at the Montefiore Medical Center. He is a Fellow of the American College of Obstetrics and Gynecology and the American College of Surgeons, as well as belonging to various research groups such as the American Association for Cancer Research and the American Society for Clinical Oncology. Dr. Einstein is a member of the GOG Vaccine subcommittee, chairs the Gynecologic Cancer Foundation National Cervical Cancer Education Campaign, sits on the Translational Research Working Group Roundtable at NIH/NCI, the NIH AIDS Malignancy Consortium, the Gynecologic Cancer Foundation Task Force for Cervical Cancer Screening and Prevention, as well as three separate committees for the Society of Gynecologic Oncologists. Dr. Einstein is very active in the clinical assessment of new immunological technologies for the treatment of gynecologic cancers.

INDUSTRY OUTLOOK

Our Outlook for the Biotech Industry is Positive in General

There are a number of strong secular growth drivers that still power the biotech industry-namely, an aging population and an enormous research and development (R&D) effort to bring new, better drugs to market. People are living longer, and many have prescription pharmaceuticals to thank for it. Recent breakthroughs in oncology, neurology, and cardiology offer sizable market opportunities. Biotechnology research is finally starting to deliver. Expanded knowledge of genomics and proteomics is attracting significant attention from some of the industry's larger players. Drug companies are finding ways to reformulate and enhance current products. This is clearly a positive for the biotech industry. Demand for

innovative medicines remains strong and biotechnology should deliver the next wave of pharmaceutical products to the market. This should allow the group to outperform the broader sector.

Licensing/partnership remain the lifeline of biotech industry. We expect to see continued partnership and in-licensing/out-licensing activities for biotech companies in the next few years.

We also expect further consolidation throughout the industry because we believe that current market environment in the Pharma/Biotech industry is favorable for M&A activities. The big pharmaceutical companies have long been faced with big challenges such as patent expiration for blockbusters, low research and development productivity, and generic competition. Platform technology and efficient R&D efforts in smaller biotech companies may be part of the solution to the challenges faced by big Pharma companies. As long as the challenges still exist in the pharmaceutical industry, the buyout of smaller biotech companies by big Pharma/giant biotech companies will continue to make sense.

For individual biotech companies, we think companies with one or more of the following fundamentals will be attractive.

- With approved products on the market which can generate cash for the company;
- With a strong balance sheet and low cash burn rate; huge amount of cash will be needed to provide funds for drug development before it can reach the market;
- With platform technologies with deep, diversified pipeline (from early to late stage drug candidates); platform technology can produce series drug candidates, and is usually worth more than a single drug candidate program. When a drug candidate is moving closer to market, it usually reduces development risks.

Investors should pay attention to those large profitable biotechnology stocks, as well as small-cap biotechnology stocks with promising pipelines.

VALUATION AND RECOMMENDATION

We think Advaxis' live, attenuated Listeria technology is a unique immunotherapeutic platform which can target various cancer indications and infectious diseases. This technology has advantages over other immunotherapies in three unique ways:

- Advaxis' Listeria-based cancer vaccine can deliver bioengineered cancer antigen fused with a unique, proprietary strong adjuvant LLO which elicits both innate and adaptive immune systems in the body to fight cancer. The immune response elicited by Advaxis' cancer vaccines has been the most comprehensive and robust so far in the industry.
- Advaxis' cancer vaccines can reduce the amount of regulatory T cells and myeloid suppressor cells which help protect tumors from attacking by cytotoxic T cells.
- Another distinctive feature of Advaxis' cancer vaccines is its ability to change the ratio between killer T-cells and regulatory T cells (the Kill Ratio) inside the tumor from a 1:1.3 to a 22.7:1.

Based on this unique platform technology, Advaxis has established a pipeline targeting a variety of cancer indications including cervical cancer/cervical dysplasia, head and neck cancer, prostate cancer and breast/brain cancers. The Company currently has two Phase II clinical trials under way and two additional Phase II trials are planned soon.

The approval of Provenge, the first active immunotherapeutic agent by Dendreon, has cleared uncertainty of clinical and regulatory paths for the whole class of such drugs. With an appropriate growth strategy in place, the Company is heading in the right direction and well positioned to grow dramatically in the coming years.

We admit that it's always difficult to value a development stage biotech company, Advaxis is no exception. However, we do think that Advaxis is undervalued. The Company should be worth more than current value of $30 million in market cap by comparing the Company with its peers in the same industry.

Currently, the Company shares are trading at about $0.16 per share which values the Company at about $36 million in market cap based on about 240 million shares outstanding. This is certainly a huge discount compared to its peers. Most small biotech companies of development stage are valued from $50 million to $500 million depending on how advanced the pipeline is and which indications the company is targeting. Advaxis is a middle stage of development biotech company, and its lead candidate ADXS11-001 is under two Phase II clinical trials and two additional Phase II trials are planned. ADXS11-001 currently targets three cancer indications: cervical cancer, cervical dysplasia and heal and neck cancers. Market potential is huge for the combined three markets. Therefore, we think at this time Advaxis should be valued at about $100 million in market cap which translate into a share price of $0.50.

We noticed recent acquisition of private BioVex by Amgen. The deal was valued at $1 billion with $425 million in upfront and up to $575 million in additional payments upon the achievement of certain regulatory and sales milestones. BioVex is developing OncoVex, an oncolytic vaccine in Phase III clinical development, for the treatment of melanoma and head and neck cancer.

Although BioVex's OncoVex is in more advanced trials (Phase III) than ADXS11-001 (Phase II), we also noticed that Advaxis has a broader technology. Therefore, this transaction convinces us that Advaxis is undervalued.

Apparently, risk is high for Advaxis at this stage, but return should also be high. Investors with high risk tolerance and relatively long investment horizon may consider Advaxis as a component of their portfolios.

RISKS

Cash Burn Concern is our Chief Concern

Advaxis has been losing money and recorded negative cash flow from operations since its inception and the Company has no meaningful revenue yet to fund its operations so far. It depends on outside funds to finance its operations. We believe the Company will continue to generate losses for the foreseeable future.

As of September 6, 2011, Advaxis had about $1.0 million in cash. The Company does not have adequate cash on hand to cover its anticipated expenses for the next 12 months. The Company raised approximately $6 million during May 2011 and $2 million during October 2011. As the Company advances its clinical programs especially the ADXS11-001 candidate for cervical cancer/CIN, R&D spending will soar. The Company may need to raise additional funds very soon. We reminder investors that equity financing will dilute existing shareholder base, and share price may suffer.

The Company's strategy is to license its clinical programs to potential partners after Phase II clinical trials. It should not be difficult to find a deal if the Phase II trial results are positive. In such a case, the cash burn concern can be greatly relieved.

Early to Middle Stage of Development Poses Higher Risks

Advaxis' Listeria platform technology has potential to target various diseases such as cancers and infectious diseases, but most of its drug candidates are at their early or middle stages of development at this point. The most advanced candidate ADXS11-001 is in Phase II clinical studies for cervical cancer and CIN. It's our belief that early to middle stage of development poses greater risks as the drug candidate must navigate through the long clinical trials and regulatory review process in order to get into market.

There is no assurance that each of Advaxis' drug candidates will reach market eventually. Any failure in clinical trials could dampen investors' enthusiasms and share price will suffer.

Trading on the OTC Market May be Volatile and Sporadic

There is currently a limited market for the Company's common stock, which is quoted on the over-the-counter market. Trading in stock quoted on the over-the-counter market is often thin and characterized by wide fluctuations in trading prices, due to many factors that may have little to do with the Company's operations or business prospects.

Moreover, the over-the-counter market is not a stock exchange, and trading of securities there is often more sporadic than the trading of securities listed on a quotation system like NASDAQ or a stock exchange like NYSE. There is no assurance that a sufficient market will develop or remain stable in the stock, in which case it could be difficult for stockholders to resell their stocks. Liquidity may be an issue for institutional investors.

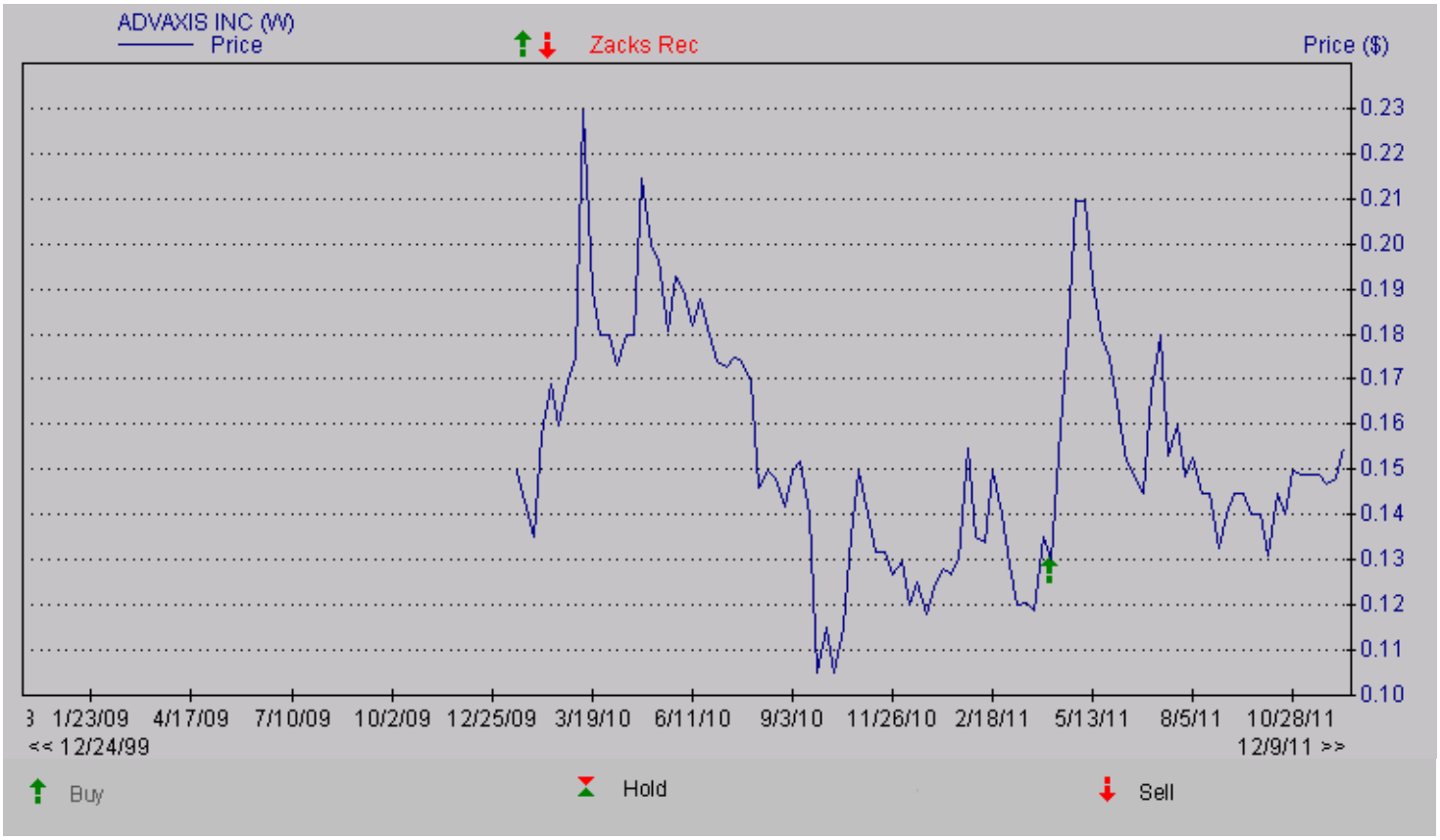
PROJECTED INCOME STATEMENT

	2010A (Oct)					2011E (Oct)					2012E (Oct)	2013E (Oct)	2014E (Oct)	2015E (Oct)
$ in million except per share data	Q1A	Q2A	Q3A	Q4A	FYA	Q1A	Q2A	Q3A	Q4E	FYE	FYE	FYE	FYE	FYE
Product Revenue	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$5.00
R&D revenue	$0.00	$0.09	$0.18	$0.24	$0.51	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$1.50	$2.00	$4.50
Total Revenues	**$0.00**	**$0.09**	**$0.18**	**$0.24**	**$0.51**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$1.50**	**$2.00**	**$9.50**
YOY Growth	-	-	-	*597.3%*	*1612.6%*	-	-	-	-	*0.0%*	*0.0%*	-	*133.3%*	*475.0%*
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Gross Income	**$0.00**	**$0.09**	**$0.18**	**$0.24**	**$0.51**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$1.50**	**$2.00**	**$9.50**
Gross Margin	-	*100.0%*	*100.0%*	*100.0%*	*100.0%*	-	-	-	-	-	-	*100.0%*	*100.0%*	*100.0%*
R&D	$1.00	$1.08	$0.85	$1.97	$4.90	$1.99	$2.45	$1.96	$2.20	$8.59	$8.50	$10.00	$12.00	$15.00
% R&D	-	-	*479.7%*	-	-	-	-	-	-	-	-	-	-	-
SG&A	$0.59	$0.78	$1.13	$1.03	$3.53	$0.98	$0.96	$1.64	$1.03	$4.61	$4.50	$5.50	$7.00	$8.50
% SG&A	-	-	*638.7%*	-	-	-	-	-	-	-	-	-	-	-
Other	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
% Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($1.6)**	**($1.8)**	**($1.8)**	**($2.8)**	**($7.9)**	**($3.0)**	**($3.4)**	**($3.6)**	**($3.2)**	**($13.2)**	**($13.0)**	**($14.0)**	**($17.0)**	**($14.0)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	($2.8)	($7.4)	$3.86	$3.1	($3.2)	$2.4	($6.4)	$7.1	($0.2)	$2.8	($0.8)	($0.8)	($1.0)	($1.0)
Pre-Tax Income	**($4.3)**	**($9.1)**	**$2.1**	**$0.3**	**($11.1)**	**($0.6)**	**($9.8)**	**$3.5**	**($3.4)**	**($10.4)**	**($13.8)**	**($14.8)**	**($18.0)**	**($15.0)**
Income taxes(benefit)	($0.3)	$0.0	$0.0	$0.0	($0.3)	($0.4)	$0.0	$0.0	$0.0	($0.4)	$0.0	$0.0	$0.0	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($4.1)**	**($9.1)**	**$2.1**	**$0.3**	**($10.8)**	**($0.2)**	**($9.8)**	**$3.5**	**($3.4)**	**($10.0)**	**($13.8)**	**($14.8)**	**($18.0)**	**($15.0)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Shares Out	*118.3*	*133.1*	*185.0*	*167.3*	*150.9*	*206.8*	*213.4*	*300.8*	*301.0*	*255.5*	*305.0*	*355.0*	*400.0*	*450.0*
Reported EPS	**($0.03)**	**($0.07)**	**$0.01**	**$0.00**	**($0.07)**	**($0.00)**	**($0.05)**	**$0.01**	**($0.01)**	**($0.04)**	**($0.05)**	**($0.04)**	**($0.05)**	**($0.03)**
YOY Growth	-	-	-	-	-					-	-	-	-	-
One time charge	$0.00	*$5.79*	*($4.13)*	*$0.00*	*$1.66*	*($3.84)*	*$5.83*	*($9.01)*	*$0.00*	*-$7.02*	*$0.00*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($4.1)**	**($3.3)**	**($2.1)**	**$0.3**	**($9.2)**	**($4.1)**	**($4.0)**	**($5.6)**	**($3.4)**	**($17.0)**	**($13.8)**	**($14.8)**	**($18.0)**	**($15.0)**
Non GAAP EPS	**($0.03)**	**($0.03)**	**($0.01)**	**$0.00**	**($0.06)**	**($0.02)**	**($0.02)**	**($0.02)**	**($0.01)**	**($0.07)**	**($0.05)**	**($0.04)**	**($0.05)**	**($0.03)**

Source: Company filing and Zacks Investment Research estimates

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HISTORICAL ZACKS RECOMMENDATIONS



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