# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

(Mark One)

| [X] QUARTERLY REPORT U            | NDER SECTION 13 OR 15(d) OF T  | HE SECURITIES EXCHANGE ACT  | OF 1934   |
|-----------------------------------|--|---|---|
|                                   | For the quarterl   | y period ended July 31, 2014  |   |
| [ ] TRANSITION REPORT U           | NDER SECTION 13 OR 15(d) OF TH   | HE SECURITIES EXCHANGE ACT  | OF 1934   |
|                                   | For the transition period fr   | rom to  |   |
|                                   | Commission   | ns file number <u>000-28489</u>   |   |
|                                   |  |   |   |
|                                   |  | AXIS, INC. istrant as specified in its charter)                                   |   |
|                                   | (Exact fiallie of reg  | istrant as specified in its charter)  |   |
|                                   | Delaware   | (IDC F  | 02-0563870  |
| (State or other jurisdiction      | on of incorporation or organization)   | (IRS Emp  | oloyer Identification No.)  |
|                                   |  | ad East, Princeton, NJ 08540  |   |
|                                   | (Address of p  | orincipal executive offices)  |   |
|                                   | · ·  | 609) 452-9813   |   |
|                                   | (Registra  | nt's telephone number)  |   |
|                                   |  |   |   |
|                                   | (Former name, former address and   | l former fiscal year, if changed since last                                       | report)   |
|                                   | s (or for such shorter period that the re  |   | 5(d) of the Securities Exchange Act of 1934 orts), and (2) has been subject to such filing    |
| be submitted and posted pursuan   |  | n 232.405 of this chapter) during the pro   | if any, every Interactive Data File required to eceding 12 months (or for such shorter period |
|                                   |  | e, an accelerated filer, a non-accelerated eporting company" in Rule 12b-2 of the | filer, or a smaller reporting company. See the Exchange Act.                                  |
| Large accelerated filer [ ]       | Accelerated filer [ ]  | Non-accelerated filer [ ]   | Smaller Reporting Company [X]   |
| Indicate by check mark whether    | the registrant is a shell company (as defi   | ined in Rule 12b-2 of the Exchange Act)   | ). Yes [ ] No [X]   |
| The number of shares of the regis | strant's common stock. \$0.001 par value   | e, outstanding as of September 2, 2014 w  | vas 19.518.409  |
|                                   | one of the state o | e, outstanding as of september 2, 2011.   | , 20 10,010, 100  |
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All other items called for by the instructions to Form 10-Q have been omitted because the items are not applicable or the relevant information is not material.

# PART I – FINANCIAL INFORMATION

# **Item 1. Condensed Financial Statements**

# ADVAXIS, INC. BALANCE SHEETS

|   |    | July 31, 2014<br>(unaudited) |    | ctober 31, 2013 |
|---|----|------------------------------|----|-----------------|
| ASSETS  |    |                              |    |                 |
| Current Assets:   |    |                              |    |                 |
| Cash  | \$ | 22,148,652                   | \$ | 20,552,062      |
| Prepaid Expenses  |    | 201,851                      |    | 31,255          |
| Deferred Expenses - current   |    | 880,708                      |    | 218,007         |
| Other Current Assets  |    | 33,182                       |    | 8,182           |
| Total Current Assets  |    | 23,264,393                   |    | 20,809,506      |
| Deferred Expenses – long term   |    | 32,353                       |    | 129,041         |
| Property and Equipment (net of accumulated depreciation)  |    | 84,271                       |    | 80,385          |
| Intangible Assets (net of accumulated amortization)   |    | 2,687,232                    |    | 2,528,551       |
| Other Assets  | _  | 38,438                       |    | 38,438          |
| TOTAL ASSETS  | \$ | 26,106,687                   | \$ | 23,585,921      |
| LIABILITIES AND SHAREHOLDERS' EQUITY  |    |                              |    |                 |
| Current Liabilities:  |    |                              |    |                 |
| Accounts Payable  | \$ | 1,741,287                    | \$ | 3,841,771       |
| Accrued Expenses  | Ψ  | 994,565                      | Ψ  | 869,260         |
| Short Term Convertible Notes and Fair Value of Embedded Derivative                                |    | 62,882                       |    | 62,882          |
| Notes Payable – Former Officer  |    | -                            |    | 163,132         |
| Total Current Liabilities   | _  | 2,798,734                    | _  | 4,937,045       |
| Total Current Elabilities   |    | 2,730,734                    |    | 4,337,043       |
| Common Stock Warrant Liability  |    | 35,084                       |    | 646,734         |
| Total Liabilities   |    | 2,833,818                    |    | 5,583,779       |
| Commitments and Contingencies   |    |                              |    |                 |
| Shareholders' Equity:   |    |                              |    |                 |
| Common Stock - \$0.001 par value; authorized 45,000,000 shares, issued and outstanding 19,514,723 |    |                              |    |                 |
| at July 31, 2014 and 13,719,861 at October 31, 2013.  |    | 19,513                       |    | 13,720          |
| Additional Paid-In Capital  |    | 107,000,382                  |    | 88,454,245      |
| Accumulated Deficit   |    | (83,747,026)                 |    | (70,465,823)    |
| Total Shareholders' Equity  |    | 23,272,869                   |    | 18,002,142      |
| TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY  | \$ | 26,106,687                   | \$ | 23,585,921      |

# ADVAXIS, INC. STATEMENTS OF OPERATIONS (unaudited)

|  | Three Months Ended July 31, |             |    | Nine Months Ended July 31, |    |              |    |              |
|--|-----------------------------|-------------|----|----------------------------|----|--------------|----|--------------|
|  | 2014 2013                   |             |    | 2014                       |    | 2013         |    |              |
| Revenue  | \$                          | <u>-</u>    | \$ | <u>-</u>                   | \$ | 1,000,000    | \$ | <u>-</u>     |
| Operating Expenses   |                             |             |    |                            |    |              |    |              |
| Research and Development Expenses                                |                             | 3,005,306   |    | 1,319,936                  |    | 6,110,095    |    | 4,411,793    |
| General and Administrative Expenses                              |                             | 2,993,739   |    | 1,733,677                  |    | 9,442,630    |    | 6,299,670    |
| Total Operating Expenses   |                             | 5,999,045   |    | 3,053,613                  |    | 15,552,725   | Ξ  | 10,711,463   |
| Loss from Operations   |                             | (5,999,045) |    | (3,053,613)                |    | (14,552,725) |    | (10,711,463) |
| Other Income (expense):  |                             |             |    |                            |    |              |    |              |
| Interest Expense   |                             | -           |    | (142,842)                  |    | (5,253)      |    | (600,004)    |
| Gain on Note retirement  |                             | -           |    | 1,723                      |    | 6,243        |    | 349,009      |
| Net changes in fair value of derivative liabilities              |                             | 210,298     |    | 1,616,919                  |    | 616,095      |    | (2,326,843)  |
| Other Income (expense)   |                             | 9,553       |    | (17,372)                   |    | 28,874       |    | (15,926)     |
| Net Loss before benefit for income taxes                         |                             | (5,779,194) |    | (1,595,185)                |    | (13,906,766) |    | (13,305,227) |
| Income tax benefit   |                             | -           | _  |                            |    | 625,563      |    | 725,190      |
| Net Loss   |                             | (5,779,194) |    | (1,595,185)                |    | (13,281,203) |    | (12,580,037) |
| Dividends attributable to preferred shares                       |                             | <u>-</u>    |    | 185,000                    |    | <u>-</u>     |    | 555,000      |
| Net Loss applicable to Common Stock                              | \$                          | (5,779,194) | \$ | (1,780,185)                | \$ | (13,281,203) | \$ | (13,135,037) |
| Net Loss per share, basic and diluted                            | \$                          | (0.30)      | \$ | (0.37)                     | \$ | (0.82)       | \$ | (3.13)       |
| Weighted Average Number of Shares Outstanding, Basic and Diluted |                             | 19,273,062  |    | 4,775,772                  |    | 16,294,134   |    | 4,190,062    |

# ADVAXIS, INC. STATEMENTS OF CASH FLOWS (unaudited)

Nine Months Ended July 31,

|   |              | July 31,      |    |              |
|---|--------------|---------------|----|--------------|
|   |              | 2014          | 2  | 013          |
| OPERATING ACTIVITIES  |              |               |    |              |
| Net Loss  | \$           | (13,281,203)  | \$ | (12,580,037) |
| Adjustments to reconcile Net Loss to net cash used in operating activities: |              |               |    |              |
| Non-cash charges to consultants and employees for options and stock         |              | 3,828,231     |    | 3,103,122    |
| Amortization of deferred financing costs                                    |              | -             |    | 28,909       |
| Amortization of discount on convertible promissory notes                    |              | -             |    | 18,392       |
| Non-cash interest expense   |              | 51            |    | 528,023      |
| (Gain) Loss on change in value of warrants and embedded derivative          |              | (616,095)     |    | 2,326,843    |
| Warrant expense   |              | 4,445         |    | 30,887       |
| Settlement expense  |              | 34,125        |    | 364,335      |
| Employee Stock Purchase Plan  |              | 5,371         |    | 21,029       |
| Depreciation expense  |              | 20,709        |    | 13,626       |
| Amortization expense of intangibles   |              | 129,434       |    | 117,920      |
| (Gain) on note retirement   |              | (6,243)       |    | (349,009)    |
| <u>Changes in operating assets and liabilities:</u>                         |              |               |    |              |
| (Increase) in prepaid expenses  |              | (170,596)     |    | (42,243)     |
| (Increase) in other current assets  |              | (25,000)      |    | (25,000)     |
| (Increase) in deferred expenses   |              | (566,013)     |    | (411,045)    |
| (Decrease) Increase in accounts payable and accrued expenses                |              | (2,105,153)   |    | 1,914,577    |
| (Decrease) in deferred rent   |              | -             |    | (4,803)      |
| (Decrease) Increase in interest payable                                     |              | (98,192)      |    | 24,840       |
| Net cash used in operating activities                                       |              | (12,846,129)  |    | (4,919,634)  |
|   |              | (==,= :=,===, |    | (1,020,001,  |
| INVESTING ACTIVITIES  |              |               |    |              |
| Proceeds from sale of equipment   |              | _             |    | 3,000        |
| Purchase of property and equipment  |              | (24,595)      |    | -            |
| Cost of intangible assets   |              | (288,115)     |    | (203,955)    |
| Net cash used in Investing Activities                                       |              | (312,710)     |    | (200,955)    |
| The coor does in investing recurrence                                       |              | (512,710)     |    | (200,333)    |
| FINANCING ACTIVITIES  |              |               |    |              |
| Proceeds from convertible notes   |              | _             |    | 2,110,500    |
| Payment of deferred offering expenses                                       |              | _             |    | (21,919)     |
| Proceeds from Officer Loan  |              | _             |    | 11,200       |
| Repayment of Officer Loan   |              | (64,926)      |    | (85,700)     |
| Proceeds from exercise of warrants  |              | 250           |    | 94,444       |
| Net proceeds of issuance of Common Stock                                    |              | 14,820,105    |    | 3,011,872    |
| Net cash provided by Financing Activities                                   |              | 14,755,429    |    | 5,120,397    |
| Net increase (decrease) in cash   |              |               |    |              |
|   |              | 1,596,590     |    | (192)        |
| Cash at beginning of period   | <del> </del> | 20,552,062    |    | 232          |
| Cash at end of period   | <u>\$</u>    | 22,148,652    | \$ | 40           |

# **Supplemental Disclosures of Cash Flow Information**

|                        | <br>Nine months ended July 31, |    |      |  |
|------------------------|--------------------------------|----|------|--|
|                        | 2014                           |    | 2013 |  |
| Cash paid for Interest | \$<br>103,445                  | \$ | 188  |  |

# Supplemental Schedule of Non-cash Investing and Financing Activities

| Nine mont     | ns en | ided |        |
|---------------|-------|------|--------|
| July          | 31,   |      |        |
| 2014          |       | 2013 |        |
| \$<br>342,309 | \$    |      | 12,307 |

|   | <br>          |    |           |  |
|---|---------------|----|-----------|--|
|   | 2014          |    | 2013      |  |
| Accounts Payable and Accrued Expenses settled with Common Stock             | \$<br>342,309 | \$ | 12,307    |  |
| Notes payable and embedded derivative liabilities converted to Common Stock | \$<br>-       | \$ | 1,962,599 |  |

# ADVAXIS, INC. NOTES TO THE FINANCIAL STATEMENTS (unaudited)

# 1. ORGANIZATION

Advaxis, Inc. ("Advaxis" or the "Company") is a clinical stage biotechnology company focused on the discovery, development and commercialization of proprietary *Lm*-LLO cancer immunotherapies. These immunotherapies are based on a platform technology that utilizes live attenuated *Listeria monocytogenes* ("*Lm*"), bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-LLO strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy as they access and direct antigen presenting cells to stimulate anti-tumor T-cell immunity, stimulate and activate the immune system with the equivalent of multiple adjuvants, and simultaneously reduce tumor protection in the tumor microenvironment to enable the T-cells to eliminate tumors. Other immunotherapies may employ individual elements of the Company's comprehensive approach, but, to its knowledge, none combine all of these elements together in a single, easily administered, well-tolerated yet comprehensive immunotherapy.

ADXS-HPV is Advaxis's lead *Lm*-LLO immunotherapy product candidate for the treatment of human papilloma virus ("HPV")-associated cancers. The Company completed a Phase 2 study in 110 patients with recurrent cervical cancer in India that demonstrated a manageable safety profile, improved survival and objective tumor responses. The Company plans to advance this immunotherapy into an adequate and well-controlled clinical trial for the treatment of women with recurrent cervical cancer. ADXS-HPV has received orphan drug designation for three HPV-associated cancers: cervical, head and neck, and anal cancer, and is being evaluated in three ongoing cooperative group and investigator-initiated clinical trials as follows: locally advanced cervical cancer (with the Gynecologic Oncology Group ("GOG")), head and neck cancer (with the Icahn School of Medicine at Mount Sinai, U.S. ("Mount Sinai")); and anal cancer (Brown University, Oncology Group, U.S. ("Brown University")). The Company also plans to initiate a Phase 1/2 clinical trial alone and in combination with MedImmune's, the global biologics research and development arm of Astrazenca, investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, in patients with previously treated locally advanced metastatic HPV-associated cervical cancer and HPV-associated head and neck cancer.

Advaxis is developing two other cancer immunotherapies. ADXS-PSA is Advaxis's *Lm*-LLO immunotherapy product candidate designed to target the PSA antigen associated with prostate cancer. Upon filing an Investigational New Drug ("IND") application, the Company plans to initiate a Phase 1/2 clinical trial alone and in combination with Merck's humanized monoclonal antibody against PD-1, pembrolizumab (MK-3475), in patients with previously treated metastatic castration-resistant prostate cancer. ADXS-cHER2 is Advaxis's *Lm*-LLO immunotherapy product candidate for the treatment of Her2 overexpressing cancers, including human and canine osteosarcoma, breast, gastric and other cancers. The Company plans to file an IND application and has received orphan drug designation for ADXS-cHER2 in osteosarcoma. Over twenty distinct additional constructs have been developed to various stages of development, developed directly by the Company and through strategic collaborations with recognized centers of excellence.

Since inception in 2002, the Company has focused its development efforts on understanding its platform technology and establishing a drug development pipeline that incorporates this technology into therapeutic cancer immunotherapies, currently those targeting HPV-associated cancer (cervical cancer, head and neck cancer and anal cancer), prostate cancer, and HER2 overexpressing cancers. Although no immunotherapies have been commercialized to date, research and development and investment continues to be placed behind the advancement of this technology. Pipeline development and the further exploration of the technology for advancement entails risk and expense. The Company anticipates that its ongoing operational costs will increase significantly as it continues conducting its clinical development program.

From inception through the period ended January 31, 2014, Advaxis Inc. was a development stage company. During the three months ended April 30, 2014, the Company exited the development stage upon its execution of a license agreement with Aratana Therapeutics Inc. ("Aratana"). This provided an upfront payment of \$1 million, which the Company recognized and earned as revenue.

# Liquidity and Financial Condition

The Company's products are being developed and have not generated significant revenues. As a result, the Company has suffered recurring losses. These losses are expected to continue for an extended period of time. However, in the nine months ended July 31, 2014, the Company recorded \$1 million in revenue pursuant to a licensing agreement with Aratana. The licensing agreement provides for potentially significant revenues based on the achievement of event-based milestones in the future. In addition, the Company completed a public offering of its Common Stock ("Common Stock") in October 2013, resulting in \$24.3 million in net proceeds, and an additional public offering in March 2014, resulting in \$12.6 million in net proceeds. Lastly, the Company received \$1.9 million in net proceeds from Aratana and Global Biopharma Inc., related to the purchase of Common Stock. The Company believes its current cash position is sufficient to fund its business plan through its fiscal year ending October 31, 2015.

The Company recognizes it will need to raise additional capital over and above the amount raised during both October 2013 and March 2014 in order to continue to execute its business plan. Subsequent to July 31, 2014, the Company may plan to continue to raise additional funds through the sales of equity securities. There is no assurance that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to the Company or whether the Company will become profitable and generate positive operating cash flow. If the Company is unable to raise sufficient additional funds, it will have to scale back its business plan, extend payables and reduce overhead until sufficient additional capital is raised to support further operations. There can be no assurance that such a plan will be successful.

# 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND BASIS OF PRESENTATION

Basis of Presentation - Unaudited Interim Financial Information

The accompanying unaudited interim condensed financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information, and in accordance with the rules and regulations of the United States Securities and Exchange Commission (the "SEC") with respect to Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The unaudited interim financial statements furnished reflect all adjustments (consisting of normal recurring accruals) which are, in the opinion of management, necessary to represent a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of the results for the full year. These unaudited interim financial statements should be read in conjunction with the financial statements of the Company for the year ended October 31, 2013 and notes thereto contained in the Company's annual report on Form 10-K for the year ended October 31, 2013, as filed with the SEC on January 29, 2014.

# Revenue Recognition

The Company is expected to derive the majority of its revenue in 2014 from patent licensing. In general, these revenue arrangements provide for the payment of contractually determined fees in consideration for the grant of certain intellectual property rights for patented technologies owned or controlled by the Company. The intellectual property rights granted may be perpetual in nature, or upon the final milestones being met, or can be granted for a defined, relatively short period of time, with the licensee possessing the right to renew the agreement at the end of each contractual term for an additional minimum upfront payment. The Company recognizes licensing fees when there is persuasive evidence of a licensing arrangement, fees are fixed or determinable, delivery has occurred and collectability is reasonably assured.

An allowance for doubtful accounts is established based on the Company's best estimate of the amount of probable credit losses in the Company's existing license fee receivables, using historical experience. The Company reviews its allowance for doubtful accounts periodically. Past due accounts are reviewed individually for collectability.

Account balances are charged off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. To date, this is yet to occur.

If product development is successful, the Company will recognize revenue from royalties based on licensees' sales of its products or products using its technologies. Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reasonably estimated and collectability is reasonably assured. If royalties cannot be reasonably estimated or collectability of a royalty amount is not reasonably assured, royalties are recognized as revenue when the cash is received.

The Company recognizes revenue from milestone payments received under collaboration agreements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, the Company has no further performance obligations relating to the event and collection is reasonably assured. If these criteria are not met, the Company recognizes milestone payments ratably over the remaining period of the Company's performance obligations under the collaboration agreement. All such recognized revenues are included in collaborative licensing and development revenue in the Company's consolidated statements of operations.

# Estimates

The preparation of financial statements in accordance with GAAP involves the use of estimates and assumptions that affect the recorded amounts of assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Significant estimates include the fair value and recoverability of the carrying value of intangible assets (patents and licenses), the fair value of options, the fair value of embedded conversion features, warrants and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates, based on historical experience and on various other assumptions that it believes to be reasonable under the circumstances. Actual results may differ from estimates.

# Concentration of Credit Risk

The Company maintains its cash in bank deposit accounts (checking) that at times exceed federally insured limits. Approximately \$21.9 million is subject to credit risk at July 31, 2014. However, these cash balances are maintained at creditworthy financial institutions. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk.

# Net Loss per Share

Basic net income or loss per common share is computed by dividing net income or loss available to common shareholders by the weighted average number of common shares outstanding during the period. Diluted earnings per share give effect to dilutive options, warrants, convertible debt and other potential Common Stock equivalents outstanding during the period. Therefore, in the case of a net loss the impact of the potential Common Stock resulting from warrants, outstanding stock options and convertible debt are not included in the computation of diluted loss per share, as the effect would be anti-dilutive. In the case of net income the impact of the potential Common Stock resulting from these instruments that have intrinsic value are included in the diluted earnings per share. The table sets forth the number of potential shares of Common Stock that have been excluded from diluted net loss per share.

|  | As of July | 31,       |
|--|------------|-----------|
|  | 2014       | 2013      |
| Warrants   | 4,587,540  | 899,494   |
| Stock Options                                    | 490,338    | 467,923   |
| Convertible Debt (using the if-converted method) | 3,354      | 478,695   |
| Total  | 5,081,232  | 1,846,112 |

# Stock Based Compensation

The Company has an equity plan which allows for the granting of stock options to its employees, directors and consultants for a fixed number of shares with an exercise price equal to the fair value of the shares at date of grant. The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. For employees and directors, the fair value of the award is measured on the grant date and for non-employees, the fair value of the award is generally measured based on contractual terms. The fair value amount is then recognized over the period during which services are required to be provided in exchange for the award, usually the vesting period.

The above stock-based compensation for employees, executives and directors is measured based on the fair value of the shares issued on the date of grant and is recognized over the requisite service period in both research and development expenses and general and administrative expenses on the statement of operations.

# Fair Value of Financial Instruments

The carrying amounts of financial instruments, including cash, accounts payable and accrued expenses approximated fair value as of the balance sheet date presented, because of the relatively short maturity dates on these instruments. The carrying amounts of the financing arrangements issued approximate fair value as of the balance sheet date presented, because interest rates on these instruments approximate market interest rates after consideration of stated interest rates, anti-dilution protection and associated warrants.

# Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers*. Amendments in this ASU create Topic 606, Revenue from Contracts with Customers, and supersede the revenue recognition requirements in Topic 605, Revenue Recognition, including most industry-specific revenue recognition guidance throughout the Industry Topics of the Codification. In addition, the amendments supersede the cost guidance in Subtopic 605-35, Revenue Recognition—Construction-Type and Production-Type Contracts, and create new Subtopic 340-40, Other Assets and Deferred Costs—Contracts with Customers. In summary, the core principle of Topic 606 is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This ASU is the final version of Proposed ASU 2011-230—Revenue Recognition (Topic 605) and Proposed ASU 2011-250—Revenue Recognition (Topic 605): Codification Amendments, both of which have been deleted. The amendments in this ASU are effective for the Company for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. The Company is currently evaluating the effects of ASU 2014-09 on the consolidated financial statements.

In June 2014, the FASB issued ASU 2014-12, *Compensation - Stock Compensation*. The amendments in this ASU apply to reporting entities that grant their employees share-based payments in which the terms of the award provide that a performance target can be achieved after the requisite service period. This ASU is the final version of Proposed ASU EITF-13D--Compensation--Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period, which has been deleted. The amendments require that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. A reporting entity should apply existing guidance in Topic 718 as it relates to awards with performance conditions that affect vesting to account for such awards. As such, the performance target should not be reflected in estimating the grant-date fair value of the award. Compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. If the performance target becomes probable of being achieved before the end of the requisite service period, the remaining unrecognized compensation cost should amount of compensation cost recognized during and after the requisite service period should reflect the number of awards that are expected to vest and should be adjusted to reflect those awards that ultimately vest. The requisite service period ends when the employee can cease rendering service and still be eligible to vest in the award if the performance target is achieved. As indicated in the definition of vest, the stated vesting period (which includes the period in which the performance target could be achieved) may differ from the requisite service period. The amendments in this ASU are effec

# 3. PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

|                            | <br>July 31, 2014 | <br>October 31, 2013 |  |
|----------------------------|-------------------|----------------------|--|
|                            | <br>(Unaudited)   |                      |  |
| Laboratory Equipment       | \$<br>333,727     | \$<br>309,132        |  |
| Accumulated Depreciation   | <br>(249,456)     | (228,747)            |  |
| Net Property and Equipment | \$<br>84,271      | \$<br>80,385         |  |

Depreciation expense for the three and nine months ended July 31, 2014 and 2013 was \$6,903, \$20,709, \$4,442 and \$13,626, respectively.

# 4. INTANGIBLE ASSETS

Under the University of Pennsylvania ("Penn") license agreements, the Company is billed actual patent expenses as they are passed through from Penn and are billed directly from our patent attorney. The following is a summary of intangible assets as of the end of the following fiscal periods:

|                          | <br>July 31, 2014 |    | October 31, 2013 |
|--------------------------|-------------------|----|------------------|
|                          | <br>(Unaudited)   |    |                  |
| License                  | \$<br>651,992     | \$ | 651,992          |
| Patents                  | <br>2,984,658     |    | 2,696,543        |
| Total intangibles        | <br>3,636,650     |    | 3,348,535        |
| Accumulated Amortization | (949,418)         |    | (819,984)        |
| Intangible Assets        | \$<br>2,687,232   | \$ | 2,528,551        |

The expirations of the existing patents range from 2014 to 2028 but the expirations can be extended based on market approval if granted and/or based on existing laws and regulations. Capitalized costs associated with patent applications that are abandoned without future value are charged to expense when the determination is made not to pursue the application. No patent applications with future value were abandoned or expired and charged to expense in the three and nine months ended July 31, 2014 or 2013. Amortization expense for licensed technology and capitalized patent costs is included in general and administrative expenses and aggregated \$44,818, \$129,434, \$40,109, and \$117,920, respectively, for the three and nine months ended July 31, 2014 and 2013.

Estimated amortization expense for the next five years is as follows:

| Year ended October 31, |              |
|------------------------|--------------|
| 2014 (Remaining)       | \$<br>41,250 |
| 2015                   | 167,500      |
| 2016                   | 167,500      |
| 2017                   | 167,500      |
| 2018                   | 167,500      |

# 5. ACCRUED EXPENSES:

The following table represents the major components of accrued expenses:

|                                 |     | July 31, 2014 |             | Oc | tober 31, 2013 |
|---------------------------------|-----|---------------|-------------|----|----------------|
|                                 |     | (1            | (Unaudited) |    |                |
| Salaries and Other Compensation |     | \$            | 733,267     | \$ | 508,979        |
| Severance Pay                   |     |               | 193,539     |    | 243,269        |
| Professional Fees               |     |               | 10,670      |    | 17,000         |
| Withholding Taxes Payable       |     |               | 57,089      |    | -              |
| Share Purchase                  |     |               | -           |    | 100,012        |
|                                 |     | \$            | 994,565     | \$ | 869,260        |
|                                 | F-8 |               |             |    |                |

# 6. SHORT-TERM CONVERTIBLE NOTES & FAIR VALUE OF EMBEDDED DERIVATIVE

As of July 31, 2014 and October 31, 2013, the Company had \$62,882 in principal outstanding on its junior subordinated convertible promissory notes that are currently overdue and are recorded as current liabilities in its balance sheet at July 31, 2014 and October 31, 2013.

# 7. NOTES PAYABLE- FORMER OFFICER:

As of October 31, 2013, the Company owed \$163,132 in principal and accrued interest to its former Chairman. On February 4, 2014, the Company paid Mr. Moore \$168,280 in principal and accrued interest, in full satisfaction of these notes. During the three and nine months ended July 31, 2014 and 2013, the Company recorded interest expense of approximately \$0, \$5,148, \$7,198 and \$24,841 in interest on these notes, respectively.

# 8. DERIVATIVE INSTRUMENTS

Warrants

A summary of changes in warrants for the nine months ended July 31, 2014 is as follows:

|   | Number of<br>Warrants | C  | hted-Average<br>ercise Price |
|---|-----------------------|----|------------------------------|
| Outstanding Warrants at October 31, 2013: | 4,265,262             | \$ | 6.71                         |
| Issued                                    | 412,539               |    | 4.97                         |
| Exercised                                 | (250)                 |    | 5.00                         |
| Expired                                   | (90,011)              |    | 11.52                        |
| Outstanding Warrants at July 31, 2014:    | 4,587,540             | \$ | 6.39                         |

At July 31, 2014, the Company had approximately 4.1 million of its total 4.6 million outstanding warrants classified as equity (equity warrants). At October 31, 2013, the Company had approximately 3.7 million of its total 4.3 million outstanding warrants classified as equity (equity warrants). At issuance, equity warrants are recorded at their relative fair values, using the Relative Fair Value Method, in the shareholders' equity section of the balance sheet. The equity warrants can only be settled through the issuance of shares and are not subject to anti-dilution provisions. During the nine months ended July 31, 2014, the Company issued 153,061 equity warrants to Aratana pursuant to a Licensing Agreement (See Footnote - 11: Shareholders' Equity). These warrants expire in March 2024 and have an exercise price of \$4.90. During the nine months ended July 31, 2014, the Company issued 100,000 equity warrants to Global BioPharma Inc. pursuant to a Stock Purchase Agreement. These warrants expire in December 2018 and have an exercise price of \$5.52. During the nine months ended July 31, 2014, the Company issued 122,400 equity warrants to Aegis Capital Corp. pursuant to a placement agent agreement. These warrants expire in March 2019 and have an exercise price of \$3.75.

At July 31, 2014, the Company had approximately 527,000 of its total 4.6 million outstanding warrants classified as liability warrants (Common Stock warrant liability). At October 31, 2013, the Company had approximately 565,000 of its total 4.3 million outstanding warrants classified as liability warrants (Common Stock warrant liability). During the nine months ended July 31, 2014, the Company issued 37,078 liability warrants, at exercise prices ranging from \$7.79 to \$9.16, as a result of existing anti-dilution provisions. The fair value of the warrant liability, as of July 31, 2014, was approximately \$35,000. The fair value of the warrant liability, at July 31, 2014 and October 31, 2013, the Company used the following inputs in its Black-Scholes Model ("BSM"):

|                 |     | 0' | 7/31/2014   | <br>10/31/2013 |  |
|-----------------|-----|----|-------------|----------------|--|
| Exercise Price: |     | \$ | 5.63-21.25  | \$ 2.76-21.25  |  |
| Stock Price     |     | \$ | 2.84        | \$<br>3.74     |  |
| Expected term:  |     |    | 8-1098 days | 61-1371 days   |  |
| Volatility %    |     |    | 31%-126%    | 99%-186%       |  |
| Risk Free Rate: |     |    | .01%-1.02%  | .035%94%       |  |
|                 | F-9 |    |             |                |  |

# Warrant Liability/Embedded Derivative Liability

# Warrant Liability

As of July 31, 2014, the Company had approximately 527,000 of its total approximately 4.6 million total warrants classified as liabilities (liability warrants). Of these 527,000 liability warrants, approximately 249,000 warrants are outstanding and approximately 278,000 warrants are exchange warrants – nonexercisable. The Company utilizes the BSM to calculate the fair value of these warrants at issuance and at each subsequent reporting date. For those warrants with exercise price reset features (anti-dilution provisions), the Company computes multiple valuations, each quarter, using an adjusted BSM, to account for the various possibilities that could occur due to changes in the inputs to the BSM as a result of contractually-obligated changes (for example, changes in strike price to account for down-round provisions). The Company effectively weights each calculation based on the likelihood of occurrence to determine the value of the warrants at the reporting date. At July 31, 2014, approximately 177,000 of the 527,000 liability warrants are subject to weighted-average anti-dilution provisions. A certain number of liability warrants contain a cash settlement provision in the event of a fundamental transaction (as defined in the Common Stock purchase warrant). Any changes in the fair value of the warrant liability (i.e. - the total fair value of all outstanding liability warrants at the balance sheet date) between reporting periods will be reported on the statement of operations.

As of October 31, 2013, the Company had approximately 565,000 of its total approximately 4.3 million total warrants classified as liabilities (liability warrants). Of these 565,000 liability warrants, approximately 287,000 warrants are outstanding and approximately 278,000 warrants are exchange warrants – nonexercisable. The Company utilizes the BSM to calculate the fair value of these warrants at issuance and at each subsequent reporting date. For those warrants with exercise price reset features (anti-dilution provisions), the Company computes multiple valuations, each quarter, using an adjusted BSM, to account for the various possibilities that could occur due to changes in the inputs to the BSM as a result of contractually-obligated changes (for example, changes in strike price to account for down-round provisions). The Company effectively weights each calculation based on the likelihood of occurrence to determine the value of the warrants at the reporting date. At October 31, 2013, approximately 203,000 of the 565,000 liability warrants are subject to anti-dilution provisions. A certain number of liability warrants contain a cash settlement provision in the event of a fundamental transaction (as defined in the Common Stock purchase warrant). Any changes in the fair value of the warrant liability (i.e. - the total fair value of all outstanding liability warrants at the balance sheet date) between reporting periods will be reported on the statement of operations.

At July 31, 2014 and October 31, 2013, the fair value of the warrant liability was \$35,084 and \$646,734, respectively. For the three months ended July 31, 2014 and 2013, the Company reported income of \$210,298 and \$1,616,919, respectively, due to changes in the fair value of the warrant liability. For the nine months ended July 31, 2014 and 2013, the Company reported income of \$616,095 and a loss of \$2,326,843, respectively, due to changes in the fair value of the warrant liability.

# Warrants with anti-dilution provisions

Some of the Company's warrants (approximately 238,000) contain anti-dilution provisions originally set at an exercise price of \$25.00 with a term of five years. As of July 31, 2014, these warrants had an exercise price of approximately \$7.79. As of October 31, 2013, these warrants had an exercise price of approximately \$9.24. If the Company issues any Common Stock, except for exempt issuances as defined in the warrant agreement for consideration less than the exercise price then the exercise price and the amount of warrant shares available would be adjusted to a new price and amount of shares per the "weighted average" formula included in the warrant agreement. For the three and nine months ended July 31, 2014, this anti-dilution provision required the Company to issue approximately 1,600 and 37,100 additional warrant shares, respectively; and the exercise price to be lowered to \$7.79. Any future financial offering or instrument issuance below the current exercise price of \$7.79 will cause further anti-dilution and re-pricing provisions in approximately 177,000 of our total outstanding warrants.

For those warrants with exercise price reset features (anti-dilution provisions), the Company computes multiple valuations, each quarter, using an adjusted BSM, to account for the various possibilities that could occur due to changes in the inputs to the BSM as a result of contractually-obligated changes (for example, changes in strike price to account for down-round provisions). The Company utilized different exercise prices of \$7.79 and \$6.50, weighting the possibility of warrants being exercised at \$7.79 between 40% and 50% and warrants being exercised at \$6.50 between 60% and 50%.

As of July 31, 2014, there were outstanding warrants to purchase 4,587,540 shares of the Company's Common Stock including exchange warrants nonexercisable to purchase 278,329 shares of the Company's Common Stock with exercise prices ranging from \$2.76 to \$21.25 per share.

# 9. STOCK OPTIONS:

A summary of changes in the stock option plan for nine months ended July 31, 2014 is as follows:

|   | Number of |    | Weighted-Average |
|---|-----------|----|------------------|
|   | Options   |    | Exercise Price   |
| Outstanding at October 31, 2013:        | 467,923   | \$ | 15.86            |
| Granted                                 | 36,000    | \$ | 4.02             |
| Exercised                               | -         | \$ | -                |
| Expired                                 | (13,585)  | \$ | 14.03            |
| Outstanding at July 31, 2014            | 490,338   | \$ | 15.04            |
| Vested and Exercisable at July 31, 2014 | 406,017   | \$ | 15.89            |

Total compensation cost related to the Company's outstanding stock options, recognized in the statement of operations for the three months ended July 31, 2014, was approximately \$212,000 of which \$76,000 was included in research and development expenses and \$136,000 was included in general and administrative expenses. For the three months ended July 31, 2013, compensation cost related to the Company's outstanding stock options was approximately \$320,000, of which \$98,000 was included in research and development expenses and \$222,000 was included in general and administrative expenses. For the nine months ended July 31, 2014, compensation cost related to the Company's outstanding stock options was approximately \$729,000 of which \$264,000 was included in research and development expenses and \$551,000 was included in general and administrative expenses. For the nine months ended July 31, 2013, compensation cost related to the Company's outstanding stock options was approximately \$2.6 million of which \$1.0 million was included in research and development expenses and \$1.6 million was included in general and administrative expenses.

The fair value of the options granted for the nine months ended July 31, 2014 and 2013 amounted to approximately \$145,000 and \$1,657,500, respectively.

As of July 31, 2014, there was \$925,005 of unrecognized compensation cost related to non-vested stock option awards, which is expected to be recognized over a remaining average vesting period of 211 days.

The aggregate intrinsic value of these outstanding options, as of July 31, 2014, was \$0.

# 10. COMMITMENTS AND CONTINGENCIES:

Resignation of Mark Rosenblum

On March 24, 2014, Mark J. Rosenblum, Senior Vice President, Chief Financial Officer and Secretary of the Company, resigned. In connection with Mr. Rosenblum's resignation, the Company and Mr. Rosenblum entered into a separation agreement (the "Separation Agreement"). The Separation Agreement provides for severance benefits of, among other things, one year's salary of \$275,000 payable in equal bi-weekly payments over a period of twelve (12) months as well as accelerated vesting of Mr. Rosenblum's stock and option awards which resulted in the Company recording approximately \$209,000 in stock compensation expense on the statement of operations representing 66,667 shares of our Common Stock (38,700 shares on a net basis after employee payroll taxes).

# Appointment of New Chief Financial Officer

On March 24, 2014, the Company's board of directors appointed Sara M. Bonstein to serve as the Company's Chief Financial Officer. The Company and Ms. Bonstein entered into an employment agreement (the "Bonstein Employment Agreement") that provides for Ms. Bonstein's appointment as Chief Financial Officer, which took effect as of such date. The Bonstein Employment Agreement provides for an initial term of one year, after which it will be automatically renewed for one year periods unless otherwise terminated by either party upon ninety (90) days written notice prior to the expiration of the applicable term. Ms. Bonstein is entitled to a base salary of \$225,000 per year (plus annual cost-of-living adjustments), which salary will be reviewed on an annual basis by the Company's Chief Executive Officer and Compensation Committee.

Ms. Bonstein voluntarily agreed to utilize a percentage of her base salary for stock compensation. Ms. Bonstein requested ninety-two and one-half percent (92.5%) of her base salary be received in the form of cash and seven and one-half percent (7.5%) of her base salary be received in the form of Common Stock of the Company. The Bonstein Employment Agreement contains provisions with respect to bonus and equity participation which are consistent with the terms of the Company's employment agreements with its other executive officers, as well as other customary covenants regarding non-solicitation, non-compete, confidentiality and works for hire. See "Employment Agreements" immediately below for a discussion of an amendment to the Bonstein Employment Agreement.

# **Employment Agreements**

In December, 2013, each of the Company's then executive officers requested to purchase stock directly from the Company at market price. To facilitate such requests, the Company amended each of the then executive officer's employment agreements so that such officers could make periodic purchases of the Company's Common Stock at fair market value. Listed below are the annual amounts to be purchased by each executive. On June 5, 2014, the Company and each of Daniel J. O'Connor, Chief Executive Officer and President, Gregory T. Mayes, Executive Vice President, Chief Operating Officer and Secretary, Robert G. Petit, Executive Vice President and Chief Scientific Officer, Sara M. Bonstein, Senior Vice President, Chief Financial Officer and Chris L. French, Vice President, Regulatory & Medical Affairs (each an "Executive"), voluntarily entered into a further amendment (each, an "Amendment" and collectively, the "Amendments") to their respective Employment Agreements (each, an "Employment Agreement"). The Amendments now provide that the respective stock purchases will occur on the last business day of each calendar month and will be effected through a direct purchase from the Company at a purchase price equal to the closing price of the Common Stock on the purchase date. The Company has not filed a Registration Statement on Form S-8 (or any other registration form) to cover the shares of Common Stock issuable pursuant to the Amendments.

The allocation between the cash and equity components of each Executive's base salary is as follows:

| Executive Officer  | Ann  Executive Officer Pr |          |    |        |                | YEAR-TO-DATE  Gross Purchase Net Purcha |        |                |  |  |
|--------------------|---------------------------|----------|----|--------|----------------|---|--------|----------------|--|--|
|                    |                           | <u> </u> |    | \$     | # of<br>shares |   | \$     | # of<br>shares |  |  |
| Daniel J. O'Connor | \$                        | 81,250   | \$ | 50,000 | 16,251         | \$                                      | 34,808 | 11,253         |  |  |
| Gregory T. Mayes   | \$                        | 19,875   | \$ | 12,231 | 3,975          | \$                                      | 9,755  | 3,161          |  |  |
| Robert G. Petit    | \$                        | 24,225   | \$ | 14,908 | 4,845          | \$                                      | 11,984 | 3,897          |  |  |
| Sara M. Bonstein   | \$                        | 16,875   | \$ | 6,490  | 2,226          | \$                                      | 4,794  | 1,646          |  |  |
| Chris L. French    | \$                        | 10,750   | \$ | 6,356  | 2,066          | \$                                      | 5,441  | 1,769          |  |  |

For the three months ended July 31, 2014, the Company recorded stock compensation expense of \$41,082 on the statement of operations representing 13,652 shares of its Common Stock (10,459 shares on a net basis after employee payroll taxes). For the nine months ended July 31, 2014, the Company recorded stock compensation expense of \$92,333 on the statement of operations representing 29,894 shares of its Common Stock (22,208 shares on a net basis after employee payroll taxes).

As to preserve the Company's cash resources, in his current Amendment, Mr. O'Connor requested to forego the scheduled increases in his base salary that were contained in his Employment Agreement. Therefore, Mr. O'Connor will not receive an annual salary increase (excluding standard cost of living adjustment) or a salary increase for closing a licensing or other strategic transaction. Mr. O'Connor's salary will remain at \$325,000.

In addition to the purchases of Common Stock set forth in the above table, Mr. O'Connor has also purchased an additional 72,676 shares of Common Stock out of his personal funds for an aggregate consideration of approximately \$313,419. These purchases consisted of the conversion of amounts due under a promissory note of approximately \$66,500 for 21,091 shares, 2013 base salary which he elected to receive in Common Stock of approximately \$182,919 for 34,752 shares, and purchases of the Company's Common Stock in the October 2013 and March 2014 public offerings of 13,500 shares for \$54,000 and 3,333 shares for \$10,000.

#### Stock Awards

In December 2013, the Company granted stock awards and restricted stock units ("RSUs") to employees, executive officers and directors under the 2011 Omnibus Incentive Plan.

- Management Team Bonuses: Executive officers received a portion of their year-end performance bonus (with a total fair value of approximately \$129,000) in the aggregate amount of 31,846 shares of the Company's Common Stock (21,389 on a net basis after employee payroll taxes).
- Equity grant to executive officers: The Company granted 525,000 shares of its Common Stock to its executive officers. Of these shares, 105,000 shares of our Common Stock (63,949 shares on a net basis after employee payroll taxes) vested immediately, with a total fair value of \$423,150, and were issued and recorded as a charge to income during the nine months ended July 31, 2014. The remaining 420,000 shares represent RSUs and are to vest in equal installments over twelve quarters such that 100% of the RSUs have vested by the third anniversary of the grant date. These RSU's are subject to availability of shares under the 2011 Omnibus Incentive Plan and are subject to forfeiture under certain conditions. During the three months ended July 31, 2014, \$342,550 was charged to stock compensation expense, representing 85,000 shares of our Common Stock (46,149 shares on a net basis after employee payroll taxes). During the nine months ended July 31, 2014, \$765,700 was charged to stock compensation expense, representing 190,000 shares of our Common Stock (110,098 shares on a net basis after employee payroll taxes), and 80,000 shares were forfeited. In the three months ended July 31, 2014, the 2011 Omnibus Incentive Plan was increased from 520,000 to 2,120,000, resulting in three quarterly vesting issuances occurring in the period.
- Equity grant to non-executive employees: The Company granted approximately \$101,250 of the aggregate base salary compensation, or 25,124 shares of Common Stock, to be issued to its non-executive employees. Of this grant, \$20,250 vested immediately and 5,025 shares of Common Stock (3,685 shares on a net basis after employee payroll taxes) were issued to non-executive employees. The remaining \$81,250, or 20,099 shares of Common Stock, represents RSUs and are to vest in equal installments over twelve quarters such that 100% of the RSUs have vested by the third anniversary of the grant date. During the three months ended July 31, 2014, \$5,817 was charged to stock compensation expense, representing 1,443 shares of our Common Stock (1,136 shares on a net basis after employee payroll taxes), and \$9,333, or 2,316 shares of Common Stock, was forfeited. During the nine months ended July 31, 2014, \$19,317 was charged to stock compensation expense, representing 4,793 shares of our Common Stock (3,792 shares on a net basis after employee payroll taxes) and \$9,333, or 2,316 shares of Common Stock, was forfeited.

All of these non-executive equity grants are currently available under the 2011 Omnibus Incentive Plan. As of July 31, 2014, all vested shares have been issued.

The Company recognizes the fair value of those vested shares in the statement of operations in the period earned.

#### Director Compensation

During December 2013, the Board of Directors deemed it advisable and in the best interests of the Company to issue shares of RSUs as compensation for all 2013 Board of Director committee meetings and to cancel any options designated for issuance related to those 2013 committee and board meetings and to further issue shares of RSUs for all fiscal years 2013 through 2016 Board of Director committee meetings in the aggregate amount of 50,000 shares of RSUs to each non-employee director (excluding Mr. Moore). The RSU grant will vest quarterly over three years such that 100 % of the RSU will be vested on the third anniversary date (December 2016). During the three and nine months ended July 31, 2014, \$251,855 was charged to stock compensation expense, representing 62,495 shares of our Common Stock. In the three months ended July 31, 2014, the 2011 Omnibus Incentive Plan was increased from 520,000 to 2,120,000, resulting in three quarterly vesting issuances occurring in the period.

During December 2013, the Board of Directors deemed it advisable and in the best interests of the Company to amend a certain provision of the consulting agreement with Mr. Moore, which took effect August 19, 2013 and issue 37,500 restricted stock units (RSU's). The RSU grant will vest quarterly over three years such that 100 % of the RSU will be vested on the third anniversary date (December 2016). Since Mr. Moore was not nominated for reelection, only 10,976 RSUs vested through his current term on the Board. Accordingly, \$46,099 was charged to stock compensation expense for the three and nine months ended July 31, 2014.

# Legal Proceedings - Iliad Research and Trading

On March 24, 2014, Iliad Research and Trading, L.P. ("Iliad") filed a complaint (the "Complaint") against us in the Third Judicial District Court of Salt Lake County, Utah, purporting to assert claims for breach of express and implied contract. Specifically, Iliad alleged that the Company granted a participation right to Tonaquint, Inc. ("Tonaquint") in a securities purchase agreement between Tonaquint and the Company, dated as of December 13, 2012 (the "Purchase Agreement"), pursuant to which Tonaquint was entitled to participate in any transaction that the Company structured in accordance with Section 3(a)(9) or Section 3(a)(10) of the Securities Act of 1933, as amended. Iliad further alleged that the settlement that the Company entered into with Ironridge Global IV, Ltd. ("Ironridge"), pursuant to which the Company issued certain shares of our Common Stock to Ironridge in reliance on the Section 3(a)(10) exemption, occurred without adequate notice for Tonaquint to exercise its participation right. In addition, Iliad alleged that it acquired all of Tonaquint's rights under the Purchase Agreement in April 2013. On May 9, 2014, the Company filed papers in support of its motion to dismiss the Complaint in its entirety. On June 2, 2014, Iliad filed an amended complaint (the "Amended Complaint"), which purported to add claims against the Company under the federal and Utah securities laws and for common law fraud. On June 30, 2014, the Company removed the action to the United States District Court for the District of Utah. On August 1, 2014, after the Court issued its Order Granting Stipulated Motion for Leave to File Second Amended Complaint, Iliad filed a Second Amended Complaint (the "SAC"), which purports to add a sixth claim for conversion. Iliad seeks "damages in an amount to be determined at trial" (though the common law fraud damages alone are alleged to be "greater than \$300,000") plus interest, attorneys' fees and costs. Iliad has also asked for punitive damages in connection with its claims under the Utah Securities Act (equal to three times its actual damages ), common law fraud and conversion. On August 22, 2014, the Company filed papers in support of its motion to dismiss the SAC in its entirety. The Company intends to continue to defend itself vigorously.

# University of Pennsylvania

On May 10, 2010, the Company entered into a second amendment to the Penn license agreement pursuant to which it acquired exclusive licenses related to its proprietary *Lm*-LLO cancer immunotherapy technology. As part of this amendment the Company exercised its option for the rights to additional patent dockets and agreed to pay historical patent costs incurred by Penn. On July 25, 2014, the Company entered into a fifth amendment to the Penn license agreement pursuant to which both parties mutually agreed to eliminate a near-term milestone payment obligation the Company had to Penn, as well as modify others relating to the development and commercialization of its *Lm*-LLO cancer immunotherapy technology. During the three months ended July 31, 2014, the Company paid Penn approximately \$9,000 under all licensing agreements. During the nine months ended July 31, 2014, the Company paid Penn approximately \$607,000 under all licensing agreements. As of July 31, 2014, the Company had no outstanding balance with Penn under all licensing agreements. As of July 31, 2014, Penn owned 28,468 shares of the Company's Common Stock.

# Consulting Agreement; Debt Conversion/Repayment

On August 19, 2013, the Company entered into a consulting agreement with Mr. Thomas A. Moore, a Director of the Company and our former Chief Executive Officer, pursuant to which Mr. Moore will continue to assist the Company in exchange for (i) receiving an aggregate of approximately \$350,000, paid in installments over the course of the one year consulting period, (ii) reimbursement by the Company for any costs associated with or incurred by Mr. Moore for participation in a group health plan and (iii) a grant of 37,500 RSUs that will vest quarterly over three years. Since Mr. Moore was not nominated for re-election, only 10,976 RSUs vested through his current term on the Board. The one-year consulting agreement automatically terminated on August 18, 2014.

On September 26, 2013, the Company entered into a debt conversion and repayment agreement with Mr. Moore with respect to the repayment and partial conversion of amounts owed to Mr. Moore under outstanding promissory notes issued pursuant to that certain Note Purchase Agreement dated September 22, 2008, as amended from time to time. The Company refers to these outstanding notes as the Moore Notes. As provided in the agreement, following the closing of the October 22, 2013 public offering: (a) the Company paid Mr. Moore \$100,000 in cash as partial repayment of the Moore Notes, (b) the Company converted one-half of the remaining balance (approximately \$162,132) using the same terms as securities being offered and sold in the October 22, 2013 offering and issued Mr. Moore 40,783 shares of our Common Stock and a five-year warrant to purchase 20,392 shares of our Common Stock at an exercise price of \$5.00 per share on October 31, 2013 and (c) within three months of the closing of the offering, the Company will pay Mr. Moore in cash the then remaining outstanding balance under the Moore Notes (approximately \$163,132). The Company paid Mr. Moore \$168,280, inclusive of additional interest expense incurred, on February 4, 2014, fully satisfying its obligations under the Moore Notes, which no longer remain outstanding.

# Numoda Corporation

On June 19, 2009 the Company entered into a Master Agreement and on July 8, 2009, it entered into a Project Agreement with Numoda Corporation ("Numoda"), to oversee Phase 2 clinical activity with ADXS-HPV for the treatment of invasive cervical cancer and CIN.

The Company is currently in discussions with Numoda relating to amounts outstanding under these agreements. Numoda has taken the position that it is owed approximately \$540,000 while the Company believes that the amount due to Numoda should be substantially less than that amount. On July 31, 2014, Advaxis and Numoda entered into a Standstill Agreement for a period of two months pursuant to which Advaxis paid Numoda \$225,000, which will be credited against any final amount Advaxis agrees or is required to pay Numoda. Advaxis and Numoda are working together to reach a final settlement regarding such outstanding amounts.

# Sale of Net Operating Losses (NOLs)

The Company may be eligible, from time to time, to receive cash from the sale of its Net Operating Losses under the State of New Jersey NOL Transfer Program. In January 2014, the Company received a net cash amount of \$625,563 from the sale of its state NOLs and research and development tax credits for the periods ended October 31, 2010 and 2011.

# 11. SHAREHOLDERS' EQUITY

**Public Offering** 

On March 31, 2014, the Company closed its public offering of 4,692,000 shares of Common Stock, including 612,000 shares that were offered and sold by the Company pursuant to the full exercise of the underwriters' over-allotment option, at a price to the public of \$3.00 per share. Total gross proceeds from the offering were \$14,076,000, before deducting underwriting discounts and commissions and other offering expenses paid by the Company of approximately \$1,400,000.

**Equity Enhancement Program** 

On September 27, 2013, the Company notified Hanover Holdings LLC that it irrevocably commits to suspend any draw-downs under the Common Stock Purchase Agreement without the prior written consent of Aegis Capital Corp. for a six month period from the closing. During the nine months ended July 31, 2014, the Company and Hanover agreed to terminate the Common Stock Purchase Agreement in exchange for the issuance of 7,080 shares of the Company's Common Stock.

Licensing Agreement - Global BioPharma Inc.

On December 9, 2013, the Company entered into an exclusive licensing agreement for the development and commercialization of ADXS-HPV with Global BioPharma, Inc. ("GBP"), a Taiwanese based biotech company funded by a group of investors led by Taiwan Biotech Co., Ltd (TBC).

GBP plans to conduct registration trials with ADXS-HPV for the treatment of advanced cervical cancer and will explore the use of Advaxis's lead product candidate in several other indications including lung, head and neck, and anal cancer.

GBP will pay Advaxis event-based financial milestones, an annual development fee, and annual net sales royalty payments in the high single to double digits. In addition, as an upfront payment, GBP made an investment in Advaxis of \$400,000 by purchasing from the Company 108,724 shares of its Common Stock at a price of \$3.68 per share, GBP also received 100,000 warrants at an exercise price of \$5.52 which expire in December 2018.

GBP will be responsible for all clinical development and commercialization costs in the GBP territory. In collaboration with Advaxis, GBP will also identify and pay the clinical trial costs for up to 150 patients with cervical cancer for enrollment in Advaxis's U.S. and GBP's Asia registrational programs for cervical cancer. GBP is committed to establishing manufacturing capabilities for its own territory and to serving as a secondary manufacturing source for Advaxis in the future. Under the terms of the agreement, Advaxis will exclusively license the rights of ADXS-HPV to GBP for Asia, Africa, and former USSR territory, exclusive of India and certain other countries, for all HPV-associated indications. Advaxis retains exclusive rights to ADXS-HPV for the rest of the world.

Licensing Agreement - Aratana Therapeutics

On March 19, 2014, the Company and Aratana entered into a definitive Exclusive License Agreement (the "Agreement"). Pursuant to the Agreement, Advaxis granted Aratana an exclusive, worldwide, royalty-bearing, license, with the right to sublicense, certain Advaxis proprietary technology that enables Aratana to develop and commercialize animal health products that will be targeted for treatment of osteosarcoma and other cancer indications in animals. Under the terms of the Agreement, Aratana paid an upfront payment to the Company, of \$1 million. As this license has stand-alone value to Aratana (who has the ability to sublicense) and was delivered to Aratana, upon execution of the Agreement, the Company recorded the \$1 million payment as licensing revenue in the three months ended April 30, 2014. Aratana will also pay the Company up to an additional \$36.5 million based on the achievement of certain milestones with respect to the advancement of products pursuant to the terms of the Agreement. In addition, Aratana may pay the Company an additional \$15 million in cumulative sales milestones pursuant to the terms of the Agreement.

Advaxis (i) issued and sold 306,122 shares of Advaxis's Common Stock to Aratana at a price of \$4.90 per share, which was equal to the closing price of the Common Stock on the NASDAQ Capital Market on March 19, 2014, and (ii) issued a ten-year warrant to Aratana giving Aratana the right to purchase up to 153,061 additional shares of Advaxis's Common Stock at an exercise price of \$4.90 per share. In connection with the sale of the Common Stock and warrants, Advaxis received aggregate net proceeds of \$1,500,000.

Based on the above licensing agreement, the Company expects to derive the majority of revenue from patent licensing if clinical development is successful. In general, these revenue arrangements provide for the payment of contractually determined fees in consideration for the grant of certain intellectual property rights for patented technologies owned or controlled by the Company. The intellectual property rights granted may be perpetual in nature, or upon the final milestones being met, or can be granted for a defined, relatively short period of time, with the licensee possessing the right to renew the agreement at the end of each contractual term for an additional minimum upfront payment. The Company recognizes licensing fees when there is persuasive evidence of a licensing arrangement, fees are fixed or determinable, delivery has occurred and collectability is reasonably assured.

An allowance for doubtful accounts is established based on the Company's best estimate of the amount of probable credit losses in the Company's existing license fee receivables, using historical experience. The Company reviews its allowance for doubtful accounts periodically. Past due accounts are reviewed individually for collectability.

Account balances are charged off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. To date, this is yet to occur.

The Company recognizes revenue from royalties based on licensees' sales of its products or products using its technologies. Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reasonably estimated and collectability is reasonably assured. If royalties cannot be reasonably estimated or collectability of a royalty amount is not reasonably assured, royalties are recognized as revenue when the cash is received.

The Company recognizes revenue from milestone payments received under collaboration agreements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, the Company has no further performance obligations relating to the event and collection is reasonably assured. If these criteria are not met, the Company recognizes milestone payments ratably over the remaining period of the Company's performance obligations under the collaboration agreement. All such recognized revenues are included in collaborative licensing and development revenue in the Company's consolidated statements of operations.

# JLS Ventures

During the three months ended July 31, 2014 the Company issued 200,000 shares of its Common Stock to JLS Ventures pursuant to the underlying agreement for investor relations services. As of July 31, 2014, there were no outstanding obligations under this agreement.

Yenson Co. Ltd

On May 15, 2014, the Company issued 45,323 shares of its Common Stock pursuant to a Securities Purchase Agreement with Yenson Co. Ltd dated August 28, 2013.

# 12. FAIR VALUE

The authoritative guidance for fair value measurements defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or the most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Market participants are buyers and sellers in the principal market that are (i) independent, (ii) knowledgeable, (iii) able to transact, and (iv) willing to transact. The guidance describes a fair value hierarchy based on the levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

- Level 1 Quoted prices in active markets for identical assets or liabilities
- Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or corroborated by observable market data or substantially the full term of the assets or liabilities
- Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the value of the assets or liabilities

The following table provides the liabilities carried at fair value measured on a recurring basis as of July 31, 2014:

| July 31, 2014  | <br>Level 1 |   | Level 2 | <br>Level 3   |    | Total   |  |
|--|-------------|---|---------|---------------|----|---------|--|
| Common stock warrant liability, warrants exercisable at \$5.63 - |             |   |         | <br>          |    |         |  |
| \$21.25 from August 2014 through March 2024                      | \$          | - | \$      | \$<br>35,084  | \$ | 35,084  |  |
|  |             |   |         |               |    |         |  |
| October 31, 2013   | Level 1     |   | Level 2 | Level 3       |    | Total   |  |
| Common stock warrant liability, warrants exercisable at \$5.63 - |             |   |         |               |    |         |  |
| \$21.25 from October 2012 through August 2017                    | \$          | - | \$      | \$<br>646,734 | \$ | 646,734 |  |

# **Common stock warrant liability:**

|   | July | 31, 2014  |
|---|------|-----------|
|   | (Ur  | naudited) |
| Beginning balance: October 31, 2013                             | \$   | 646,734   |
| Issuance of additional warrants due to anti-dilution provisions |      | 4,445     |
| Change in fair value  |      | (616,095) |
| Balance at July 31, 2014  | \$   | 35,084    |

# 13. SUBSEQUENT EVENTS

Issuance of shares to Consultant

On September 2, 2014, the Company issued 1,179 shares of its Common Stock to an accredited investor as payment for consulting services rendered.

**Employment Agreements** 

On August 29, 2014, the Company issued 2,507 shares of its Common Stock to its Executive Officers, pursuant to their Employment Agreements.

# ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Cautionary Note Regarding Forward Looking Statements

The Company has included in this Quarterly Report certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 concerning the Company's business, operations and financial condition. "Forward-looking statements" consist of all non-historical information, and the analysis of historical information, including the references in this Quarterly Report to future revenues, collaborative agreements, future expense growth, future credit exposure, earnings before interest, taxes, depreciation and amortization, future profitability, anticipated cash resources, anticipated capital expenditures, capital requirements, and the Company's plans for future periods. In addition, the words "could", "expects", "anticipates", "objective", "plan", "may affect", "may depend", "believes", "estimates", "projects" and similar words and phrases are also intended to identify such forward-looking statements. Such factors include the risk factors included in other filings by the Company with the SEC and other factors discussed in connection with any forward-looking statements.

Actual results could differ materially from those projected in the Company's forward-looking statements due to numerous known and unknown risks and uncertainties, including, among other things, the Company's ability to raise capital, unanticipated technological difficulties, the length, scope and outcome of our clinical trial, costs related to intellectual property, cost of manufacturing and higher consulting costs, product demand, changes in domestic and foreign economic, market and regulatory conditions, the inherent uncertainty of financial estimates and projections, the uncertainties involved in certain legal proceedings, instabilities arising from terrorist actions and responses thereto, and other considerations described as "Risk Factors" in other filings by the Company with the SEC. Such factors may also cause substantial volatility in the market price of the Company's Common Stock. All such forward-looking statements are current only as of the date on which such statements were made. The Company does not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

# Overview

Advaxis is a clinical-stage biotechnology company developing multiple cancer immunotherapies based on its proprietary platform intended to redirect the immune system to kill cancer. Our *Lm*-LLO technology, using bioengineered live attenuated *Listeria monocytogenes* bacteria, is the only known cancer immunotherapy shown in preclinical studies to neutralize Tregs and MSDCs, both of which protect the tumor microenvironment from immunologic attack and contribute to tumor growth.

# ADXS-HPV Franchise

ADXS-HPV is a *Lm*-LLO immunotherapy directed against HPV and designed to target cells expressing the HPV gene E7. It is currently under investigation in three HPV-associated cancers: recurrent or persistent cervical cancer, head and neck cancer, and anal cancer, both as a monotherapy and in combination with investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736.

# Cervical Cancer

We completed a Phase 2 clinical study that was conducted in India in 110 women with recurrent cervical cancer. The final results, were presented at the 2014 American Society of Clinical Oncology (ASCO) Annual Meeting, and showed that 22% (24/109) of the patients were long-term survivors ("LTS") of greater than 18 months. 18% (16/91) of patients were alive for more than 24 months. Of the 109 patients treated in the study, LTS included not only patients with tumor shrinkage but also patients who had experienced increased tumor burden. 17% (19/109) of the patients in the trial had recurrence of disease after at least two prior treatments for their cervical cancer; these patients comprised 8% (2/24) of LTS. Among the LTS, 25% (3/11) of patients had an ECOG performance status of 2, a patient population that is often times excluded from clinical trials because of their poor survival.

We have completed an End-of-Phase 2 ("EOP2") meeting with the United States Food and Drug Administration ("FDA"). The purpose of the EOP2 meeting was to discuss ADXS-HPV's preclinical data, Chemistry, Manufacturing and Controls ("CMC") and clinical program prior to moving ADXS-HPV forward into the next phase of clinical development in cervical cancer. At the meeting, the FDA provided guidance on our CMC activities and clinical development plan. We are in dialogue with the FDA to incorporate this valuable guidance into our planned registration program and we plan to submit a Phase 3 protocol for a special protocol assessment ("SPA"). We are planning to initiate an adequate and well-controlled clinical trial in cervical cancer in 2015 to support a Biologics License Application ("BLA") submission in the U.S.

The adequate and well-controlled Phase 3 clinical trial that we are planning to conduct will compare repeating cycles of ADXS-HPV against physician's choice of chemotherapy, in women with recurrent or persistent cervical cancer who have progressed after receiving prior approved therapy. This population has a tremendous medical need because no available treatment has been shown to improve their survival. The goal of the study would be to provide clinically relevant life extension to these patients. We have entered into a Master Services Agreement with inVentiv Clinical Health ("inVentiv") to serve as its global Contract Research Organization ("CRO") for this study.

The Gynecologic Oncology Group (GOG) of the National Cancer Institute (NCI) is independently conducting a single arm Phase 2 study of ADXS-HPV as monotherapy in women with recurrent/refractory cervical cancer in the US. We have agreed to provide clinical material to support this study but do not control the conduct of the study.

We have received Institutional Review Board (IRB) approval at Georgia Regents University ("GRU") Cancer Center to initiate a Phase 1/2 trial evaluating higher doses, repeat cycles and immunologic effect in patients with recurrent cervical cancer.

We recently entered into a clinical trial collaboration agreement with MedImmune LLC ("MedImmune"), the global biologics research and development arm of AstraZeneca, where we plan to collaborate on a Phase 1/2 study to evaluate safety and efficacy of MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, in combination with Advaxis's investigational *Lm*-LLO cancer immunotherapy, ADXS-HPV, as a combination treatment for patients with advanced, recurrent or refractory HPV associated cervical cancer and HPV-associated head and neck cancer.

ADXS-HPV has received orphan drug designation for invasive Stage II-IVb cervical cancer.



# Head and Neck Cancer

The safety and efficacy of ADXS-HPV is being evaluated in a Phase 1/2 study under an investigator-sponsored IND at Mount Sinai in patients with HPV-positive head and neck cancer. This clinical trial is the first study to evaluate the effects of ADXS-HPV in patients when they are initially diagnosed with HPV-associated head and neck cancer, prior to receiving any chemotherapy or radiation for their cancer.

As stated above, we recently entered into a clinical trial collaboration agreement with MedImmune to collaborate on a Phase 1/2 study to evaluate safety and efficacy of MEDI4736 in combination with ADXS-HPV as a combination treatment for patients with advanced, recurrent or refractory HPV associated cervical cancer and HPV-associated head and neck cancer. We are preparing to file an IND and associated protocol with the FDA in the coming months.

ADXS-HPV has received orphan drug designation for HPV-associated head and neck cancer.

# **Anal Cancer**

The safety and efficacy of ADXS-HPV is being evaluated in a Phase 1/2 study under an investigator-sponsored IND by Brown University in patients with HPV-associated anal cancer.

ADXS-HPV has received orphan drug designation for HPV-associated anal cancer.

#### ADXS-PSA Franchise

# **Prostate Cancer**

ADXS-PSA is a *Lm*-LLO immunotherapy designed to target the PSA antigen associated with prostate cancer.

We recently entered into a clinical trial collaboration and supply agreement with Merck & Co. ("Merck"), to evaluate the safety and efficacy of ADXS-PSA as monotherapy and in combination with Merck's investigational anti PD-1 antibody MK-3475 (pembrolizumab), in a Phase 1/2 study in patients with previously treated metastatic, castration-resistant prostate cancer. We are preparing to file an IND and associated protocol with the FDA in the coming months.

#### ADXS-cHER2 Franchise

# Pediatric Osteosarcoma

ADXS-cHER2 is a *Lm*-LLO immunotherapy designed to target the Her2 gene which is overexpressed in some cancers such as human and canine osteosarcoma, breast, gastric and other. We are completing the activities required for an IND filing in 2014 with plans to initiate a Phase 1 study in patients with HER2-overexperssing cancers. Thereafter, we intend to initiate a clinical development program with ADXS-cHER2 for the treatment of pediatric osteosarcoma.

In a veterinarian clinical study, pet dogs with naturally occurring osteosarcoma treated with ADXS-cHER2 after the standard of care showed a statistically significant prolonged overall survival benefit compared with dogs that received standard of care without ADXS-cHER2. Both veterinary and human osteosarcoma specialists consider canine osteosarcoma to be the best model for human osteosarcoma.

Pediatric osteosarcoma affects about 400 children and teens in the U.S. every year, representing a small but significant unmet medical need that has seen little therapeutic improvement in decades. Pediatric osteosarcoma is considered a rare disease and may qualify for regulatory incentives including, but not limited to, orphan drug designation, patent term extension, market exclusivity, and development grants. Given the limited availability of new treatment options for pediatric osteosarcoma, and that it is an unmet medical need affecting a very small number of patients in the U.S. annually, we believe that, subject to regulatory approval, the potential to be on the market may be accelerated.

ADXS-HPV has received orphan drug designation for osteosarcoma.

# Canine Osteosarcoma

A product license request has been filed by Aratana for ADXS-cHER2 (also known as AT-014 by Aratana) for the treatment of canine osteosarcoma with the United States Department of Agriculture ("USDA"). While the USDA has no specific obligation to respond within a prescribed timeframe, the companies expect a response from the USDA to the request for a product license within the next several months. Aratana has been granted exclusive worldwide rights by Advaxis to develop and commercialize ADXS-cHER2 in animals.

# Lm-LLO Combination Franchise

# ADXS-HPV and MEDI4736

As stated above, we recently entered into a clinical trial collaboration agreement with MedImmune, the global biologics research and development arm of AstraZeneca, where we plan to collaborate on a Phase 1/2 study to evaluate safety and efficacy of MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, in combination with Advaxis's investigational *Lm*-LLO cancer immunotherapy, ADXS-HPV, as a combination treatment for patients with advanced, recurrent or refractory HPV associated cervical cancer and HPV-associated head and neck cancer.

# ADXS-PSA and MK-3475

As stated above, we recently entered into a clinical trial collaboration agreement with Merck to evaluate the safety and efficacy of ADXS-PSA as monotherapy and in combination with Merck's anti PD-1 antibody pembrolizumab, in a Phase 1/2 study in patients with previously treated metastatic, castration-resistant prostate cancer. We are preparing to file an IND and associated protocol with the FDA in the coming months.

# Lm-LLO and GRU

We have a non-clinical research agreement with GRU which provides research collaboration of the in vitro effect of our *Lm*-LLO cancer immunotherapy technology evaluating it in combination with other immunotherapies, including, but not limited to, anti-PD-L1 & anti-PD-1 immune checkpoint inhibitors.

# Corporate

We continue to invest in the development of our platform technology and utilize our capital most efficiently. For example, we recently entered into an amendment with Penn, where both parties mutually agreed to eliminate a near-term milestone payment obligation we had to Penn, as well as modify others relating to the development and commercialization of our *Lm*-LLO cancer immunotherapy technology. In addition, to ensure we appropriately support our development efforts, we entered into a master service agreement with inVentiv, a leading global CRO, for the clinical development of our immunotherapy products. inVentiv is a suitable partner, providing full CRO services to execute our clinical studies while offering competitive rates and, pending regulatory approval, we have the option to leverage inVentiv's significant commercialization capabilities.

We have been added to the Russell Microcap Index, which is widely used by investment managers and institutional investors for index funds and as benchmarks for active investment strategies.

# RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED JULY 31, 2014 AND 2013

#### Revenue

We did not record any revenue for the three months ended July 31, 2014 and 2013.

# Research and Development Expenses

We make significant investments in research and development in support of our development programs both clinically and pre-clinically. Research and development costs are expensed as incurred and primarily include salary and benefit costs, third-party grants, fees paid to clinical research organizations, and supply costs. Research and development expense was \$3.0 million for the three months ended July 31, 2014, compared with \$1.3 million for the three months ended July 31, 2013, an increase of \$1.7 million. The increase was primarily a result of higher third-party costs, specifically related to the ADXS-HPV cervical cancer program and ADXS-cHER2 preclinical support, as well as higher stock compensation costs.

We anticipate a significant increase in research and development expenses as a result of our intended expanded development and commercialization efforts primarily related to clinical trials and product development. In addition, we expect to incur expenses in the development of strategic and other relationships required to license, manufacture and distribute our product candidates when they are approved.

# General and Administrative Expenses

General and administrative expenses primarily include salary and benefit costs for employees included in our finance, legal and administrative organizations, outside legal and professional services, and facilities costs. General and administrative expense was \$3.0 million for the three months ended July 31, 2014, compared with \$1.7 million for the three months ended July 31, 2013, an increase of \$1.3 million. The increase was primarily a result of higher stock compensation costs from Common Stock that was issued after the number of authorized shares under the 2011 Omnibus Incentive Plan was increased from 520,000 to 2,120,000, and non-cash investor relations costs.

# Interest Expense

Interest expense was \$0 for the three months ended July 31, 2014, compared with \$142,842 for the three months ended July 31, 2013. The decrease was a result from the significant reduction in overall debt from approximately \$3.6 million in outstanding principal at July 31, 2013 to \$62,882 in outstanding principal at July 31, 2014. Substantially all of the outstanding principal at July 31, 2013 was converted or repaid during the fiscal year ended October 31, 2013, resulting in a significant decrease in interest expense for the three months ended July 31, 2014.

# Other Income / (Expense)

Other income was \$9,553 for the three months ended July 31, 2014, compared to other expense of \$17,372 for the three months ended July 31, 2013. Interest income earned for the three months ended July 31, 2014 reflected interest income earned on the Company's savings account balance. Interest expense for the three months ended July 31, 2013 reflected the result of unfavorable changes in foreign exchange rates relating to transactions with certain vendors.

# Gain on Note Retirement and Accounts Payable

Non-cash income for gain on note retirement and accounts payable was \$0 for the three months ended July 31, 2014, compared to non-cash income for gain on note retirement and accounts payable of \$1,723 for the three months ended July 31, 2013. Non-cash income earned for the three months ended July 31, 2013 primarily resulted from the settlement of outstanding payables with shares of our Common Stock at a discount.

# Changes in Fair Values

Change in fair value was \$210,298 for the three months ended July 31, 2014, compared with change in fair value of \$1,616,919 for the three months ended July 31, 2013. The non-cash income from changes in the fair value of the warrant liability recorded for the three months ended July 31, 2014 were a result of a decrease in the number of liability warrants in addition to lower volatility of the Company's stock price used in the BSM. The non-cash income from changes in the fair value of the warrant liability recorded for the three months ended July 31, 2013 were a result of a decrease in the fair value of each liability warrant due to a decrease in our share price from \$8.31 at April 30, 2013 to \$3.50 at July 31, 2013 in addition to a smaller range of share prices used in the calculation of the BSM volatility input. This was slightly offset by non-cash expenses related to the mark-to-market of convertible notes, accounted for under Fair Value accounting.

# RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED JULY 31, 2014 AND 2013

#### Revenue

During our second fiscal quarter ended April 30, 2014, we transitioned from a development stage company to an operating company. On March 19, 2014, we and Aratana entered into a definitive Agreement pursuant to which we granted Aratana an exclusive, worldwide, royalty-bearing, license, with the right to sublicense, certain, Advaxis proprietary technology that enables Aratana to develop and commercialize animal health products that will be targeted for treatment of osteosarcoma and other cancer indications in animals. Under the terms of the Agreement, Aratana paid us an upfront payment of \$1 million. As this license has stand-alone value to Aratana (who has the ability to sublicense) and was delivered to Aratana upon execution of the Agreement, we properly recorded the \$1 million payment as licensing revenue for the nine months ended July 31, 2014.

We did not record any revenue for the nine months ended July 31, 2013.

# Research and Development Expenses

We make significant investments in research and development in support of our development programs both clinically and pre-clinically. Research and development costs are expensed as incurred and primarily include salary and benefit costs, third-party grants, fees paid to clinical research organizations, and supply costs. Research and development expense was \$6.1 million for the nine months ended July 31, 2014, compared with \$4.4 million for the nine months ended July 31, 2013, an increase of \$1.7 million. The increase was primarily a result of higher third-party costs, specifically related to ADXS-HPV cervical cancer program and ADXS-cHER2 preclinical support.

We anticipate a significant increase in research and development expenses as a result of our intended expanded development and commercialization efforts primarily related to clinical trials and product development. In addition, we expect to incur expenses in the development of strategic and other relationships required to license, manufacture and distribute our product candidates when they are approved.

# General and Administrative Expenses

General and administrative expenses primarily include salary and benefit costs for employees included in our finance, legal and administrative organizations, outside legal and professional services, and facilities costs. General and administrative expense was \$9.4 million for the nine months ended July 31, 2014, compared with \$6.3 million for the nine months ended July 31, 2013, an increase of \$3.1 million. The increase was primarily a result of higher stock compensation costs from Common Stock that was issued after the number of authorized shares under the 2011 Omnibus Incentive Plan was increased from 520,000 to 2,120,000, and non-cash investor relations costs.

# Interest Expense

Interest expense was \$5,253 for the nine months ended July 31, 2014, compared with \$600,004 for the nine months ended July 31, 2013. The decrease was a result of the significant reduction in overall debt from approximately \$3.6 million in outstanding principal at July 31, 2013 to \$62,882 in outstanding principal at July 31, 2014. In addition, we recorded \$157,150 in non-cash interest expense, in the prior period, related to the issuance of 3.5 million shares (Commitment Fee Shares) under the Hanover Purchase Agreement.

# Other Income / (Expense)

Other income was \$28,874 for the nine months ended July 31, 2014, compared to other expense of \$15,926 for the nine months ended July 31, 2013. Interest income earned for the nine months ended July 31, 2014 reflected interest income earned on the Company's savings account balance. Interest income earned for the nine months ended July 31, 2013 reflected the result of approximately \$5,100 in interest income from payments made to us under the terms of a convertible promissory note, more than offset by expense of approximately \$21,000 related to unfavorable changes in foreign exchange rates relating to transactions with certain vendors.

# Gain on Note Retirement and Accounts Payable

Non-cash income for gain on note retirement and accounts payable was \$6,243 for the nine months ended July 31, 2014, compared to non-cash income for gain on note retirement and accounts payable of \$349,009 for the nine months ended July 31, 2013. Non-cash income earned for the nine months ended July 31, 2014 primarily resulted from the settlement of outstanding payables with shares of our Common Stock at a discount. Non-cash income earned for the nine months ended July 31, 2013 primarily resulted from the settlement of outstanding payables with shares of our Common Stock at a discount. This income was partially offset by charges incurred related to the conversion of notes into shares of our Common Stock by investors.

# Changes in Fair Values

Change in fair value was \$616,095 for the nine months ended July 31, 2014, compared with change in fair value of \$2.3 million for the nine months ended July 31, 2013. The non-cash income from changes in the fair value of the warrant liability recorded for the nine months ended July 31, 2014 were a result of a decrease in the fair value of each liability warrant due to a decrease in our share price from \$3.74 at October 31, 2013 to \$2.72 at July 31, 2014 in addition to a lower volatility of the Company's stock price used in the BSM. Changes in the fair value of the warrant liability recorded for the nine months ended July 31, 2013 were a result of non-cash expense of approximately \$1.2 million from the mark-to-market of our convertible promissory notes, accounted for under fair value accounting. In addition, we recorded non-cash expense of approximately \$1.1 million resulting from the number of outstanding liability warrants increasing during the prior period in addition to a larger range of share prices used in the calculation of the BSM Model volatility input.

Potential future increases or decreases in our stock price will result in increased or decreased warrant and embedded derivative liabilities, respectively, on our balance sheet and therefore increased or decreased expenses being recognized in our statement of operations in future periods.

# Income Tax Benefit

We may be eligible, from time to time, to receive cash from the sale of our Net Operating Losses ("NOLs") under the State of New Jersey NOL Transfer Program. In the nine months ended July 31, 2014, we received a net cash amount of \$625,563 from the sale of our state NOLs and research & development tax credits for the periods ended October 31, 2010 and 2011.

In the nine months ended July 31, 2013, we received a net cash amount of \$725,190 from the sale of our state NOLs and research & development tax credits for the periods through October 31, 2010.

# **Liquidity and Capital Resources**

Since our inception through July 31, 2014, the Company has reported accumulated net losses of \$83.7 million and recurring negative cash flows from operations. We anticipate that we will continue to generate significant losses from operations for the foreseeable future.

Cash used in operating activities for the nine months ending July 31, 2014 was \$12.8 million (including proceeds from the sale of our state NOLs and R&D tax credits of approximately \$0.6 million) primarily from spending associated with our clinical trial programs and general & administrative spending. Total spending approximated \$13.9 million, including one-time non-recurring costs associated with our October 2013 financing, March 2014 financing, certain compensation costs and the settlement of legal claims.

Cash used in investing activities, for the nine months ended July 31, 2014, was \$312,710 resulting from legal cost spending in support of our intangible assets (patents) and costs paid to Penn for patents.

Cash provided by financing activities, for the nine months ended July 31, 2014, was \$14.8 million, primarily resulting from the public offering of 4,692,000 shares of Common Stock at \$3.00 per share, resulting in net proceeds of \$12.6 million. In addition, the Company sold 306,122 shares of Advaxis's Common Stock to Aratana at a price of \$4.90 per share, resulting in net proceeds of \$1.5 million. The Company also received \$0.4 million from the sale of Common Stock under Stock Purchase Agreement with GBP and issued GBP 108,724 shares of our Common Stock.

For the nine months ending July 31, 2013, we issued to certain accredited investors (including JMJ Financial) convertible promissory notes in the aggregate principal amount of \$2,138,277 for an aggregate net purchase price of \$2,110,500. These convertible promissory notes were issued with either original issue discounts ranging from 15% to 25% or are interest-bearing and are convertible into shares of our Common Stock. Some of these convertible promissory notes were issued along with warrants. Most of the convertible promissory notes have subsequently converted into Common Stock. In addition, during the nine months ended July 31, 2013, Mr. Moore loaned our company \$11,200 under the Moore Notes. The Company repaid Mr. Moore \$85,700 under the Moore Notes.

During the nine months ended July 31, 2013, we issued 17,657 shares of our Common Stock, to accredited investors, at a price per share of \$4.375, resulting in total net proceeds of \$77,250.

During the nine months ended July 31, 2013, we issued 348,724 shares of our Common Stock to Hanover in connection with the settlement of drawdowns pursuant to the Hanover Purchase Agreement, at prices ranging from approximately \$3.32 to \$7.48 per share. The per share price for such shares was established under the terms of the Hanover Purchase Agreement. We received total net proceeds of \$2,934,624 in connection with these drawdowns.

Our limited capital resources and operations to date have been funded primarily with the proceeds from public and private equity, debt financings, NOL tax sales and income earned on investments and grants. We have sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future, due to the substantial investment in research and development. As of July 31, 2014 and October 31, 2013, we had an accumulated deficit of \$83,747,026 and \$70,465,823, respectively and shareholders' equity of \$23,272,869 and \$18,002,142, respectively.

The Company believes its current cash position is sufficient to fund its business plan through our fiscal year ending October 31, 2015. This assessment is based on current estimates and assumptions regarding our clinical development program and business needs. Actual results could differ materially from this projection. Subsequent to July 31, 2014, the Company may plan to continue to raise additional funds through the sales of debt and/or equity securities as needed.

The Company recognizes it will need to raise additional capital over and above the amounts raised both during October 2013 and March 2014 in order to continue to execute its business plan. There is no assurance that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to the Company or whether the Company will become profitable and generate positive operating cash flow. If the Company is unable to raise sufficient additional funds, it will have to scale back its business plan, extend payables and reduce overhead until sufficient additional capital is raised to support further operations. There can be no assurance that such a plan will be successful.

# **Off-Balance Sheet Arrangements**

As of July 31, 2014, we had no off-balance sheet arrangements.

# **Critical Accounting Estimates**

The preparation of financial statements in accordance with GAAP accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts and related disclosures in the financial statements. Management considers an accounting estimate to be critical if:

- it requires assumptions to be made that were uncertain at the time the estimate was made, and
- changes in the estimate of difference estimates that could have been selected could have material impact in our results of operations or financial condition.

While we base our estimates and judgments on our experience and on various other factors that we believe to be reasonable under the circumstances, actual results could differ from those estimates and the differences could be material. The most significant estimates impact the following transactions or account balances: stock compensation, warrant valuation and dilution caused by anti-dilution provisions in the warrants and other agreements.

# Stock Based Compensation

We account for stock-based compensation using fair value recognition and record stock-based compensation as a charge to earnings net of the estimated impact of forfeited awards. As such, we recognize stock-based compensation cost only for those stock-based awards that are estimated to ultimately vest over their requisite service period, based on the vesting provisions of the individual grants.

The process of estimating the fair value of stock-based compensation awards and recognizing stock-based compensation cost over their requisite service period involves significant assumptions and judgments. We estimate the fair value of stock option awards on the date of grant using the BSM for the remaining awards, which requires that we make certain assumptions regarding: (i) the expected volatility in the market price of our Common Stock; (ii) dividend yield; (iii) risk-free interest rates; and (iv) the period of time employees are expected to hold the award prior to exercise (referred to as the expected holding period). As a result, if we revise our assumptions and estimates, our stock-based compensation expense could change materially for future grants.

Stock-based compensation for employees, executives and directors is measured based on the fair value of the shares issued on the date of grant and is to be recognized over the requisite service period in both research and development expenses and general and administrative expenses on the statement of operations.

# Fair Value of Financial Instruments

The carrying amounts of financial instruments, including cash, receivables, accounts payable and accrued expenses approximated fair value, as of the balance sheet date presented, because of the relatively short maturity dates on these instruments. The carrying amounts of the financing arrangements issued approximate fair value, as of the balance sheet date presented, because interest rates on these instruments approximate market interest rates after consideration of stated interest rates, anti-dilution protection and associated warrants. The estimate of fair value of such financial instruments involves the exercise of significant judgment and the use of estimates by management.

# Derivative Financial instruments

We do not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. We evaluate all of our financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. The determination of fair value requires the use of judgment and estimates by management. For stock-based derivative financial instruments, we used the BSM which approximated the binomial lattice options pricing model to value the derivative instruments at inception and on subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the instrument could be required within 12 months of the balance sheet date. The variables used in the model are projected based on our historical data, experience, and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for changes in the valuation of the warrant derivative liability.

# **New Accounting Pronouncements**

Management does not believe that any other recently issued, but not yet effective accounting pronouncements, if adopted, would have a material impact on the accompanying consolidated financial statements.

# ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

# Not Applicable

# ITEM 4. CONTROLS AND PROCEDURES

# Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, we conducted an evaluation, under the supervision and with the participation of our chief executive officer and chief financial officer of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act). Based upon this evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is: (1) accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure; and (2) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. In conjunction with this evaluation, we initiated the development of control design documents and are currently reviewing the recommendations and will implement change as appropriate.

# Changes in Internal Control over Financial Reporting

During the quarter ended July 31, 2014, there were no significant changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

# **PART II - OTHER INFORMATION**

# ITEM 1. LEGAL PROCEEDINGS

The Company is from time to time involved in legal proceedings in the ordinary course of our business. The Company does not believe that any of these claims or proceedings against us is likely to have, individually or in the aggregate, a material adverse effect on the financial condition or results of operations. Refer to Note 10: Commitments and Contingencies to our financial statements included elsewhere in this Quarterly Report for more information on legal proceedings.

# ITEM 1A. RISK FACTORS

There were no material changes in any risk factors previously disclosed in the Company's Annual Report on Form 10-K or in the Company's Form 10-Q filed with the Securities and Exchange Commission on January 29, 2014 and June 10, 2014, respectively.

# ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

During the period covered by this report, we have issued unregistered securities to the persons as described below. None of these transactions involved any underwriters, underwriting discounts or commissions, except as specified below, or any public offering, and we believe that each transaction was exempt from the registration requirements of the Securities Act of 1933 by virtue of Section 3(a)(9) or Section 4(a)(2) thereof and/or Regulation D promulgated thereunder. All recipients had adequate access to information about us. We have not furnished information under this item to the extent that such information previously has been included under Item 3.02 in a Current Report on Form 8-K.

On May 1, 2014, the registrant issued 7,061 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On May 2, 2014, the registrant issued 8,615 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On May 13, 2014, the registrant issued 100,000 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On May 15, 2014, the registrant issued 70,323 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On June 2, 2014, the registrant issued 1,179 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On June 16, 2014, the registrant issued 2,411 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On July 1, 2014, the registrant issued 5,590 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On July 23, 2014, the registrant issued 1,179 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On August 1, 2014, the registrant issued 4,869 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On August 1, 2014, the registrant issued 4,869 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

# **ITEM 5. OTHER INFORMATION**

On September 8, 2014, Advaxis and IDT Biologika GmbH ("IDT") entered into a definitive Manufacturing Services Agreement (the "IDT Agreement") pursuant to which IDT has agreed to manufacture, produce and supply ADXS-HPV (the "Product"), as well as perform other work specified under a work plan and work packages, which may be amended by the parties from time-to-time during the term of the IDT Agreement. IDT is required to conduct manufacturing activities in accordance with cGMP (except with respect to certain products deemed "Development Products"), applicable specifications, the terms of the IDT Agreement and the terms of a quality agreement. Additionally, IDT is required to manufacture the Product and may not subcontract any performance of services without Advaxis's prior consent. In exchange for IDT's services, Advaxis is required to pay IDT in accordance with the provisions set forth in the IDT Agreement and the applicable work package. IDT is responsible for compliance with German federal, state and local tax requirements relating to payments made by Advaxis to IDT under the IDT Agreement. Under the IDT Agreement, IDT agreed to reserve the necessary resources and capacities needed to perform the services.

Pursuant to the IDT Agreement, Advaxis granted IDT a non-exclusive, royalty-free, license to use certain of Advaxis's intellectual property in connection with IDT's performance of services under the IDT Agreement. IDT granted Advaxis an irrevocable, fully paid, non-exclusive worldwide license, with the right to grant and authorize sublicenses, under any and all of IDT's intellectual property that IDT incorporates pursuant to the IDT Agreement into the master production record or into the specifications, to make, have made, use, have used, sell, offer for sale, have sold, import, have imported, export, have exported, develop, have developed, commercialize, and have commercialized any product.

Under the terms of the IDT Agreement, in the event that, pursuant to the work plan, IDT requires new capital equipment to conduct manufacturing or other services, the parties will negotiate in good faith and mutually agree upon the terms for procurement of such equipment. Advaxis will own such new equipment and will reimburse IDT for the costs of such equipment. In addition, during such time period that such equipment is the property of Advaxis, IDT is responsible for maintaining and repairing such equipment, and Advaxis is required to pay the reasonable costs of such maintenance and repair. At the expiration or termination of the IDT Agreement, the items of such equipment that are installed as part of an IDT production line will be retained and be owned by IDT, and IDT will be required to pay Advaxis the depreciated book value of such items of equipment. With respect to the items of equipment that are not so installed at the expiration or termination of the IDT Agreement in an IDT production line, the parties will agree to either (a) ship such equipment to Advaxis, at Advaxis's expense; (b) dispose of such items of equipment, at Advaxis's expense, (c) continue to retain the items of such equipment as Advaxis's property to be used for manufacturing the Product, or (d) pay Advaxis the depreciated book value of such items of equipment and thereafter retain and own such items of equipment.

Additionally, under the IDT Agreement, Advaxis has the sole right and responsibility for filing all documents with applicable regulatory authorities and for taking any other actions that may be required or necessary in order to obtain regulatory approval from such regulatory authorities for the use of the Product in clinical trials or in order to obtain marketing authorization for the Product. IDT is responsible for all communications with any regulatory authority or other governmental authority or agency relating to maintaining facility licensure. Furthermore, Advaxis will be responsible for recalls of the Product, and IDT is required to fully cooperate with respect to same. All costs of a Product recall or other corrective measure related to the Product is the sole responsibility of Advaxis, except to the extent such recall is due to a defective product caused by IDT, in which event IDT shall also be liable for the direct costs of such recall.

Each party has the right to terminate the IDT Agreement, and in the case of Advaxis any work plan, in whole or in part at any time by providing prior notice of termination to the other party in the event that the other party (a) defaults in the performance of any material obligation and fails to cure such default within sixty days after receiving a notice specifying such default, (b) enters into bankruptcy proceedings or (c) is not able to procure or maintain the insurance coverage as required by the Agreement.

The term of the IDT Agreement begins on the Agreement's effective date. The IDT Agreement will remain in full force and effect for an initial period of eighty-four months after the date on which the first regulatory approval (the "First Regulatory Approval Date") is granted by any regulatory authority for the use, distribution or sale of any Product in the respective end market for which such regulatory approval has been granted, provided, that at the end of each consecutive twelve month period after the First Regulatory Approval Date, the term of the IDT Agreement will automatically extend by for a twelve month period unless either party provides at least thirty-six months' advance notice to the other party of termination of the Agreement. Notwithstanding the foregoing, in the event that no First Regulatory Approval Date occurs within thirty-six months after the IDT Agreement's effective date, the IDT Agreement will automatically terminate at the end of such thirty-six month period.

On August 22, 2011, the Board of Directors of Advaxis adopted the 2011 Omnibus Incentive Plan, which was subsequently approved by our stockholders on September 27, 2011, and further amended and approved by the stockholders on August 13, 2012 and July 9, 2014. On September 8, 2014, the Board of Directors of Advaxis approved an Amended and Restated 2011 Omnibus Incentive Plan to consolidate the prior amendments and further amend the plan. The Amended and Restated 2011 Omnibus Incentive Plan is unchanged from the previously approved plan, as amended, except for a change in the annual per-person award limitation to provide that in any fiscal year of the company (during any part of which the plan is in effect), no participant may be granted (i) options or stock appreciation rights with respect to more than Two Hundred Fifty Thousand (250,000) shares or (ii) restricted stock units, performance shares and/or other stock-based awards with respect to more than Two Hundred Fifty Thousand (250,000) shares (subject to adjustment as provided in Section 10(c) on the plan). This is not a complete statement of the Amended and Restated 2011 Omnibus Incentive Plan. A copy of the full Amended and Restated 2011 Omnibus Incentive Plan is attached to this quarterly report as Exhibit 10.4.

On September 9, 2014, Advaxis announced the completion of an EOP2 meeting with the FDA for its lead *Lm*-LLO cancer immunotherapy, ADXS-HPV, for the treatment of recurrent cervical cancer in women. The purpose of the EOP2 meeting was to discuss ADXS-HPV's preclinical data, CMC and clinical program prior to moving ADXS-HPV forward into the next phase of clinical development in cervical cancer. At the meeting, the FDA provided guidance on the Company's CMC activities and clinical development plan. The Company is in dialogue with the FDA to incorporate this valuable guidance into its planned registration program and the Company plans to submit a Phase 3 protocol for a SPA. The Company is planning to initiate an adequate and well-controlled clinical trial in cervical cancer in 2015 to support a BLA submission in the U.S.

The adequate and well-controlled Phase 3 clinical trial that the Company is planning to conduct will compare repeating cycles of ADXS-HPV against physician's choice of chemotherapy, in women with recurrent or persistent cervical cancer who have progressed after receiving prior approved therapy. This population has a tremendous medical need because no available treatment has been shown to improve their survival. The goal of the study would be to provide clinically relevant life extension to these patients. The Company has entered into a Master Services Agreement with inVentiv to serve as its global CRO for this study.

# ITEM 6. EXHIBITS.

- 3.1 Amended and Restated Certificate of Incorporation. Incorporated by reference to Annex C to DEF 14A Proxy Statement filed with the SEC on May 15, 2006.
- 3.2 Certificate of Designations of Preferences, Rights and Limitations of Series A Preferred Stock of the registrant, dated September 24, 2009. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on September 25, 2009.
- 3.3 Certificate of Designations of Preferences, Rights and Limitations of Series B Preferred Stock of the registrant, dated July 19, 2010. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on July 20, 2010.
- 3.4 Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on August 16, 2012. Incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the SEC on August 17, 2012.
- 3.5 Certificate of Amendment of the Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on July 11, 2013 (reverse stock split). Incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the SEC on July 15, 2013.
- 3.6 Certificate of Amendment of the Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on July 12, 2013 (reverse stock split). Incorporated by reference to Exhibit 3.2 to Current Report on Form 8-K filed with the SEC on July 15, 2013.
- 3.7 Certificate of Amendment of the Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on July 9, 2014. Incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the SEC on July 10, 2014.
- 3.8 Amended and Restated Bylaws. Incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-QSB filed with the SEC on September 13, 2006.
- 10.1\*\*\* Clinical Trial Collaboration Agreement, dated July 21, 2014, by and between Advaxis Inc. and MedImmune, LLC.
- 10.2\* 5<sup>th</sup> Amendment to the Amended & Restated Licensed Agreement, dated July 25, 2014, by and between Advaxis Inc. and University of Pennsylvania.
- Amendment No. 2 to the Advaxis Inc. 2011 Omnibus Incentive Plan, effective July 9, 2014. Incorporated by reference to Annex A to Current Report on Schedule 14A filed with the SEC on May 20, 2014.
- 10.4\* Amended and Restated 2011 Omnibus Incentive Plan, dated September 8, 2014.
- Amendment No. 2, dated as of June 5, 2014, to the Employment Agreement by and between Advaxis, Inc. and Daniel J. O'Connor. Incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-Q filed with the SEC on June 10, 2014.
- Amendment No. 2, dated as of June 5, 2014, to the Employment Agreement by and between Advaxis, Inc. and Gregory T. Mayes. Incorporated by reference to Exhibit 10.5 to Quarterly Report on Form 10-Q filed with the SEC on June 10, 2014.
- 10.7‡ Amendment No. 2, dated as of June 5, 2014, to the Employment Agreement by and between Advaxis, Inc. and Robert G. Petit. Incorporated by reference to Exhibit 10.6 to Quarterly Report on Form 10-Q filed with the SEC on June 10, 2014.
- Amendment No. 2, dated as of June 5, 2014, to the Employment Agreement by and between Advaxis, Inc. and Chris L. French. Incorporated by reference to Exhibit 10.7 to Quarterly Report on Form 10-Q filed with the SEC on June 10, 2014.
- Amendment No. 1, dated as of June 5, 2014, to the Employment Agreement by and between Advaxis, Inc. and Sara M. Bonstein. Incorporated by reference to Exhibit 10.8 to Quarterly Report on Form 10-Q filed with the SEC on June 10, 2014.
- 31.1\* Certification of Chief Executive Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002
- 31.2\* Certification of Chief Financial Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002
- 32.1\* Certification of Chief Executive Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002
- 32.2\* Certification of Chief Financial Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002
- 101.INS\*\* XBRL INSTANCE DOCUMENT
- 101.SCH\*\* XBRL TAXONOMY EXTENSION SCHEMA DOCUMENT
- 101.CAL\*\* XBRL TAXONOMY EXTENSION CALCULATION LINKBASE DOCUMENT
- 101.DEF\*\* XBRL TAXONOMY EXTENSION DEFINITION LINKBASE DOCUMENT
- 101.1 LAB\*\* XBRL TAXONOMY EXTENSION LABEL LINKBASE DOCUMENT
- 101.PRE\*\* XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE DOCUMENT

<sup>\*</sup> Filed herewith

\*\* Furnished herewith

\*\*\* Filed herewith. Confidential treatment requested under 17 C.F.R. §§200.80(b)(4) and Rule 24b-2. The confidential portions of this exhibit have been omitted and are marked accordingly. The confidential portions have been provided separately to the SEC pursuant to the confidential treatment request. ‡ Denotes management contract or compensatory plan or arrangement.

# **SIGNATURES**

In accordance with the requirements of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: September 8, 2014

ADVAXIS, INC.

Registrant

By: /s/ Daniel J. O'Connor

Daniel J. O'Connor Chief Executive Officer

By: /s/ Sara M. Bonstein

Sara M. Bonstein Chief Financial Officer

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NOTE: CERTAIN PORTIONS OF THIS DOCUMENT HAVE BEEN MARKED "[C.I.]" TO INDICATE THAT CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR THIS CONFIDENTIAL INFORMATION. THE CONFIDENTIAL PORTIONS HAVE BEEN OMITTED AND SUBMITTED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

### CLINICAL TRIAL COLLABORATION AGREEMENT

This Collaboration Agreement (this "Agreement") is entered into as July 21, 2014 ("Effective Date"), by and among MedImmune, LLC, a limited liability company having a place of business at One MedImmune Way, Gaithersburg, MD 20878 USA ("MedImmune"), and Advaxis, Inc., a New Jersey Limited Liability Company, having a place of business at 305 College Road East, Princeton, New Jersey 08540 USA ("ADVAXIS"). Each of ADVAXIS and MedImmune may be referred to in this Agreement as a "Party," and collectively, they may be referred to as the "Parties."

**WHEREAS**, MedImmune is in the business of developing therapeutic drugs for the treatment of human health conditions and has identified a certain MedImmune Development Product that has therapeutic potential in the treatment of cancer, and wishes to collaborate with a third party for a clinical study of such MedImmune Development Product;

**WHEREAS**, ADVAXIS is in the business of developing *Listeria monocytogenes* (Lm) immunotherapy therapeutic products for the treatment of human health conditions and has identified an ADVAXIS Development Product that has therapeutic potential in the treatment of cancer, and wishes to collaborate with a third party for a clinical study of such ADVAXIS Development Product;

**WHEREAS**, the Parties believe that there may be potential therapeutic benefit from the combination of the MedImmune Development Product and the ADVAXIS Development Product in the treatment of cancer;

**WHEREAS**, each Party has established a clinical research program to conduct clinical trials of cancer immunotherapies and wishes to perform a clinical trial using combination of the MedImmune Development Product and ADVAXIS Development Product;

WHEREAS, the Parties see a mutually beneficial opportunity to collaborate in such a combination clinical trial as more detailed herein.

**NOW, THEREFORE**, in consideration of the mutual covenants set forth in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties intending to be legally bound agree as follows:

# 1. **DEFINITIONS**.

- 1.1 Defined Terms. Capitalized terms used in this Agreement and not otherwise defined herein shall have the meaning set forth below.
- "AAA" shall have the meaning set forth in Section 2.2(c)(ii).
- "ADVAXIS Invention" shall have the meaning set forth in Section 4.3.
- "ADVAXIS Development Product" means ADXS11-001 which is a live, attenuated *Listeria monocytogenes* (*Lm*) based vector bioengineered to secrete an antigen-adjuvant fusion (tLLO-E7) protein consisting of a truncated fragment of the listeriolysin (tLLO) fused to human papillomavirus type 16 E7 (HPV16-E7). "ADVAXIS Representatives" shall mean ADVAXIS, its Affiliates and each of their respective directors, managers, officers, employees and agents.
- "Affiliate" means any person, corporation, or other entity that controls, is controlled by, or is under common control with a Party. A corporation or other entity shall be regarded as in control of another corporation or entity if it owns or directly or indirectly controls more than fifty percent (50%) of the voting stock or other ownership interest of the other corporation or entity, or if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or other entity or the power to elect or appoint fifty percent (50%) or more of the members of the governing body of the corporation or other entity.

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- "Alliance Manager" shall have the meaning set forth in Section 2.2(g).
- "Antibody" means, depending on the context it is used in, a molecule or genetic material that encodes such a molecule where the binding activity of the molecule comprises complementarity determining regions. This includes, but is not limited to, a molecule or genetic material encoding such a molecule comprising or containing:
  - at least one immunoglobulin variable domain;
  - parts of such domains or modifications thereof; or
  - the genetic materials that encode either one of the 1<sup>st</sup> and 2<sup>nd</sup> sub-bullets right before this 3<sup>rd</sup> bullet.
- "Anti-bribery and Anti-corruption Laws" means the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010 and any other applicable anti-bribery and anti-corruption laws in any country in the Territory.
- "Anti-Corruption Policies" means the AstraZeneca Global Policy on Ethical Interactions, as the same may be amended, modified or supplemented from time to time.
- "Applicable Law(s)" means any national, supra-national, federal, state or local laws, treaties, statutes (including but not limited to the FD&C Act, EMA regulations, and any laws, regulations and guidelines pertaining to human subject protection and privacy), ordinances, rules and regulations, including any rules, regulations, guidance or guidelines having the binding effect of law, or requirements of Regulatory Authorities, national securities exchanges or securities listing organizations, government authorities, courts, tribunals, agencies other than Regulatory Authorities, legislative bodies and commissions that are in effect in any part of the Territory from time to time during the term of the Agreement.

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"Background Intellectual Property" means, individually and collectively, all Intellectual Property Rights of any of the Parties in existence at any time prior to the Effective Date provided to the other Party for use in, or which is necessary or useful for performing, the Sponsored Clinical Trial. In the case of ADVAXIS, Background Intellectual Property shall include but not be limited to, rights in and to the ADVAXIS Development Product and in and to any INDs relating to the ADVAXIS Development Product. In the case of MedImmune, Background Intellectual Property shall include but not be limited to, rights in and to the MedImmune Development Product and in and to any INDs relating to the MedImmune Development Product.

"Business Day" means any day other than a Saturday or Sunday that is not a national holiday in the United States.

"CFR" means the United States Code of Federal Regulations.

"Clinical Development and Commercialization Agreement" shall have the meaning set forth in Section 3.4.1.

"Confidential Information" means any confidential and proprietary scientific, technical, commercial, marketing or other information (as hereinafter defined) furnished, directly or indirectly, and whether in writing, orally or otherwise, by one Party ("Disclosing Party") to the other Party ("Receiving Party") pursuant to or in connection with this Agreement and/or arising from the activities or transactions contemplated by this Agreement, and/or relating to Proprietary Materials (as hereinafter defined). All information disclosed and to be protected hereunder as Confidential Information, if disclosed in writing or other tangible form, shall be designated as confidential and proprietary at the time of delivery, or if disclosed orally or in other intangible form, shall be identified as confidential and proprietary in writing within thirty (30) days of disclosure.

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- "Data" means the information, data or results arising from the activities under this Agreement, including the Study Data and any analyses of the foregoing.
- "Derivative(s)" means substances created which constitute an unmodified functional subunit or product expressed by the ADVAXIS Development Product. Some examples of Derivatives include: subclones of unmodified cell lines, purified or fractionated subsets of the ADVAXIS Development Product, proteins expressed by DNA/RNA, or monoclonal antibodies secreted by a hybridoma cell line.
- "Development Products" means the ADVAXIS Development Product and/or the MedImmune Development Product.
- "Expert" shall have the meaning set forth in Section 2.2(c)(ii).
- "FDA" means the United States Food and Drug Administration, or any successor thereto.
- "FD&C Act" means the United States Federal Food, Drug and Cosmetic Act of 1938 and applicable regulations promulgated thereunder, as amended from time to time.
- "Forecast" means a twelve (12) month written rolling forecast that is approved by the JSC that includes the best estimate of the following information for the applicable twelve (12) months: (i) the quantity of MedImmune Development Product reasonably needed to supply the Sponsored Clinical Trial for the applicable period; (ii) the dose; (iii) the frequency of dosing; (iv) the number of patient subjects to be enrolled; (v) the duration of the Sponsored Clinical Trial; and (vi) the number of Study Sites to perform the Sponsored Clinical Trial and the country in which each Study Site is based.

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"Good Clinical Practices", "Good Laboratory Practices" and "Good Manufacturing Practices" shall have the meaning set forth in FDA rules, regulations and guidelines and any other applicable corresponding rules, regulations and guidelines in any other Territory.

"Government Official" means any person employed by or acting on behalf of a government, government-controlled entity or public international organization; any political party, party official or candidate; any person who holds or performs the duties of an appointment, office or position created by custom or convention; and any person who holds him/herself out to be the authorized intermediary of a Government Official.

"HIPAA" means the United States Health Insurance Portability and Accountability Act of 1996 and its applicable regulations.

"HPV" shall mean human papillomavirus.

"ICH Guidelines" means the guidelines of the International Conference on Harmonization.

**"IND"** means an investigational new drug application, as defined in the FD&C Act, filed with the FDA and necessary for beginning clinical trials of any product in humans or any clinical trial application (CTA) or other equivalent application or other documentation filed with any Regulatory Authority of a country other than the U.S. required to begin clinical trials of any product in humans in that country.

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"Intellectual Property Right(s)" means any and all ideas, inventions, discoveries, know-how, data, information, results, databases, documentation, reports, materials, writings, designs, computer software, processes, principles, methods, techniques and other information, including Patents, trade secrets, trademarks, service marks, trade names, registered designs, design rights, copyrights (including rights in computer software and database rights), whether registered or not, and all legal means of establishing rights in and to and the aforesaid rights or property similar to any of the foregoing, in any part of the world, together with the right to apply for the registration of any such rights.

"Investigator" means an individual who conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a subject).

"IRB" shall have the meaning set forth in Section 3.1(e).

"JSC" shall have the meaning set forth in Section 2.1.

"Joint MedImmune-ADVAXIS Invention" shall have the meaning set forth in Section 4.4.

"MedImmune Clinical Representative" shall have the meaning set forth in Section 3.1(b).

"MedImmune Compound Invention" shall have the meaning set forth in Section 4.2.

"MedImmune Development Product" means the MEDI-4736 antibody binding to Programmed DEATH-Ligand1 (PD-L1), also known as cluster of differentiation 274 (CD274) or B7 homolog1 (B7-H1).

"MedImmune Drug Supply" means the amount of the MedImmune Development Product supplied pursuant to Section <u>3.3.1</u> which meets the standards of Good Manufacturing Practice for use in human clinical trials in the country in the Territory.

"MedImmune Representatives" shall mean MedImmune, its Affiliates and each of their respective directors, managers, officers, employees and agents.

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- "Negotiation Period" means a period beginning upon the completion of the Sponsored Clinical Trial and receipt by MedImmune of the last final report for the Sponsored Clinical Trial and, unless extended in writing by the Parties, ending one-hundred twenty (120) days thereafter.
- "Net Sales" means with respect to Royalty Bearing Product the gross amount invoiced to a Third Party for Royalty Bearing Product by ADVAXIS or its Affiliates or any of their respective licensees or sub-licensees, and in each case to extent included in the gross amount invoiced after deducting the following related to the applicable Royalty Bearing Product:
- (a) trade, quantity and/or cash discounts, allowances or rebates, including promotional, service or similar discounts or rebates and discounts or rebates to governmental or managed care organizations, to the extent actually given or allowed in connection with Royalty Bearing Product;
  - (b) credits or allowances actually granted with respect to Royalty Bearing Products by reason of rejection, defects, recalls or returns, or chargebacks;
- (c) any tax, tariff, duty or government charge (including any Indirect Taxes, import or customs duty or similar tax or government charge, but excluding any income tax) levied on the sale, transfer, delivery and/or transportation of the Royalty Bearing Product; and
- (d) a reasonable allowance for bad debt, which allowance for bad debt for a calendar year shall be adjusted in the last Quarter of a calendar year to reflect the amount of bad debt actually written off for sale of Royalty Bearing Product for that calendar year.

ADVAXIS shall make periodic adjustments of the amounts described in (a) through (d) to its initial accruals of such amounts applied in a prior calendar Quarter to reflect amounts actually incurred or taken.

Net Sales shall be determined in accordance with the accounting convention used by ADVAXIS consistently applied.

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- "Patents" means (a) issued patents, (b) provisional patent applications filed in any jurisdiction, (b) non-provisional patent applications filed in any jurisdiction, whether or not corresponding to or claiming priority from any other patent and/or patent applications, (c) divisional, continuations and continuations-in-part of a patent and/or patent application, (d) all reissues, re-examination certificates, registrations, confirmations, extensions, substitutions, renewals and supplementary protection certificates of any patents and/or patent applications, and (e) all foreign counterparts of the patents and patent applications.
- "PD-1" means Programmed Death-1 receptor, also identified as CD279, and encoded by the PDCD1 gene.
- "PD-1 Antibody" means an antibody binding to PD-1.
- "PD-L1" means Programmed Death-Ligand 1, also identified as CD274 or B7-H1, and encoded by the CD274 gene.
- "PD-L1 Antibody" means an antibody binding to PD-L1.
- "Person" means any individual, corporation, association, partnership (general or limited), joint venture, trust, estate, limited liability company, limited liability partnership, unincorporated organization, government (or any agency or political subdivision thereof) or other legal entity or organization.
- "Pharmacovigilance Agreement" shall mean that certain pharmacovigilance agreement referenced in Section 3.1(j) of this Agreement.

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- "Principal Investigator" means [c.i.] at Georgia Regents University, or as may be amended or changed upon written consent of both Parties.
- "Progeny" means unmodified descendants from the ADVAXIS Development Product, such as virus from virus, cell from cell, or organism from organism.
- "Protocol Concept Sheet" means the draft proposed protocol of the Sponsor Clinical Trial, attached to this Agreement as Attachment A, which shall be the basis for the JSC approved final protocol.
- "Publication" shall have the meaning set forth in Section <u>5.6</u>.
- "Quality Assurance Agreement" shall mean that certain quality assurance agreement(s) referenced in Section 3.1(j) of this Agreement.
- "Quarter" means each period of three (3) months ending on March 31, June 30, September 30, or December 31, and "Quarterly" shall be construed accordingly.
- "Regulatory Approval" means any applicable and all approvals from Regulatory Authorities in a country which are required to market and sell Development Products in such country.
- "Regulatory Authority" means any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, with authority over the distribution, importation, exportation, manufacture, production, use, storage, transport, investigational clinical testing or sale of a drug for use in humans, in the Territory, including but not limited to the FDA.
- "Representatives" means, with respect to a Party, such Party's Affiliates and its and their respective officers (including directors), trustees, employees, agents, vendors and sub-contractors, and with respect to either Party acting as a Sponsor of a Sponsored Clinical Trial, any other Person engaged in the conduct of the Sponsored Clinical Trials as permitted hereunder.

- "Royalty Bearing Product" means any HPV immunotherapy (including, but not limited to, an ADVAXIS Development Product that has Regulatory Approval to be used in conjunction or in combination with any PD-1 Antibody or PD-L1 Antibody.
- "Samples" means all biological samples, including blood, tissue, tumor biopsy tissue, cells and any other biological materials, collected during the Sponsored Clinical Trial.
- "Samples Analysis/Assays Procedures" shall mean the analysis and/or assays the Parties wish to perform on the Samples pursuant to Section 3.3.9 and listed in Attachment B of this Agreement.
- "Secondary Research" shall have the meaning set forth in Section 3.3.9.
- "SEC" shall mean the United States Securities Exchange Commission.
- "**Sponsor**" shall have the meaning set forth in Section <u>3.1(a)</u>.
- "Sponsored Clinical Trial" means a clinical trial with respect to a combination of MedImmune Development Product and ADVAXIS Development Product in accordance with the protocol approved by the JSC or any amendment to such protocol approved by the JSC and the budget and any amendments to such budget provided to MedImmune for review.
- "Study Data" means all of the data and results in the form they have been received by ADVAXIS which have been collected by Investigators and/or Study Sites in the conduct of the Sponsored Clinical Trials and which are supplied by Investigators and/or Study Sites to ADVAXIS.
- "Study Sites" means the institutions selected to participate in a Sponsored Clinical Trial pursuant to this Agreement.

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- "Study Subjects" shall mean any patient that has consented to and is enrolled in a Sponsored Clinical Trial.
- "Term" shall have the meaning set forth in Section 6.1.
- "Territory" means the United States of America.
- "Third Party" means any Person, or Affiliate thereof, that is neither a signatory to this Agreement nor an Affiliate of a signatory to this Agreement.
- "WMA" shall have the meaning set forth in Section 3.1(e).

# 2. JOINT STEERING COMMITTEE.

2.1 A joint steering committee ("JSC") shall be responsible and have decision making authority for (i) approving a protocol for the Sponsored Clinical Trial pursuant to the Protocol Concept Sheet attached to this Agreement as Appendix A; (ii) amending any such approved protocol; (iii) approving forecast for MedImmune Drug Supply and (iv) without limiting either Party's rights in Section 6.2, suspending or terminating the Sponsor Clinical Trial for cause. The JSC shall also be responsible for discussing and monitoring the progress of the Sponsored Clinical Trial. For the avoidance of doubt, the JSC shall not have the power or authority to amend the terms and conditions of this Agreement and/or any of the rights and obligations of a Party under this Agreement. Through the JSC and prior to the first patient screened in the Sponsored Clinical Trial, a copy of the budget for the Sponsored Clinical Trial and any amendments thereafter shall be provided to MedImmune for review. ADVAXIS shall reasonably consider any comments or suggestions made by MedImmune to the budget and associated amendments.

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- 2.2 (a) The JSC shall be composed of four (4) members with MedImmune appointing one half of the members and ADVAXIS one half of the members, which number of members may be adjusted by the JSC as long as there is an even number of members.
- (b) The JSC shall meet at least once each calendar Quarter in person or by video conference. A quorum for the conduct of business shall consist of at least one representative of MedImmune and at least one representative of ADVAXIS. Each of MedImmune and ADVAXIS shall have one vote, and subject to Section 2.2(c) all decisions shall be reached by a unanimous vote. The Parties shall cause the JSC to approve a protocol consistent with Appendix A within sixty (60) days of the signing of this Agreement.
- (c) If there is a tie vote in the JSC, ADVAXIS and MedImune agree to exert all reasonable efforts, including escalation to individuals at each Party at the Vice President level or higher, to arrive at a mutually acceptable resolution. In the event that there is a tie vote that is not resolved within thirty (30) days, then the tie vote shall be resolved by arbitration in accordance with the following procedure:
- (i) either Party shall have the right to elect, upon written notice to the other, to arbitrate the tie vote dispute in accordance with this Section 2.2(c);
- (ii) upon receipt of notice of the request for arbitration, the Parties shall promptly negotiate in good faith to appoint a mutually acceptable, disinterested, conflict-free individual not affiliated with either Party, and with the scientific, technical, regulatory and/or clinical experience with respect to the tie vote dispute necessary to resolve such dispute (an "Expert"). If the Parties are not able to agree within seven (7) days after the receipt by a Party of the written request in the immediately preceding sentence, the American Arbitration Association (or any successor entity) (the "AAA"), shall be responsible for selecting an Expert within seven (7) days of being approached by a Party. The fees and costs of the Expert and the AAA (or such other entity) shall be shared equally by the Parties;

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- (iii) Within fourteen (14) days after the designation of the Expert, the Parties shall each simultaneously submit to the Expert and one another a written statement of their respective positions on such disagreement. Each Party shall have seven (7) days from receipt of the other Party's submission to submit a written response thereto, which shall include any scientific and technical information in support thereof. The Expert shall have the right to meet with the Parties, either alone or together, as necessary to make a determination; and
- (iv) No later than thirty (30) days after the designation of the Expert, the Expert shall make a determination by selecting the resolution proposed by one of the Parties that as a whole is the most fair and reasonable to the Parties in light of the totality of the circumstances and shall provide the Parties with a written statement setting forth the basis of the determination in connection therewith. The decision of the Expert shall be final and conclusive, absent manifest error.
- (d) The JSC shall keep accurate minutes which shall record all decisions and all actions recommended or taken. The Parties shall alternate responsibility for the preparation of the draft minutes on an annual basis. All records of the JSC shall at all times be available to both Parties.
- (e) ADVAXIS shall provide the JSC with Quarterly written reports regarding activities performed under the Sponsored Clinical Trial for the applicable calendar Quarter and activities to be performed in the next calendar Quarter and any other information reasonably requested by the JSC.

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- (f) Each Party shall be responsible for all travel and related costs and expenses for its members to attend meetings of and otherwise participate in the JSC.
- (g) Each Party shall appoint one (1) individual, who is not a member of the JSC, to take on the responsibility of alliance manager ("Alliance Manager") for that Party. The purpose of the Alliance Manager shall be to help facilitate the collaboration between the Parties as contemplated by this Agreement. Responsibilities include, but are not limited to, assisting the JSC with setting the agenda and meetings times, communicating decisions to their Party's senior executives and being the point of contact for communications between the Parties.

# 3 Obligations and Responsibilities of the Parties with respect to the Sponsored Clinical Trial.

- 3.1 ADVAXIS Obligations and Responsibilities with respect to the Sponsored Clinical Trial are as follows:
- (a) Except for MedImmune bearing the cost and expense for supplying the MedImmune Development Product (as well as the costs relating to the proprietary assays performed by MedImmune or a third party on behalf of MedImmune on the MedImmune Development Product or on Samples from Study Subjects (as identified in Appendix A, the Protocol Concept Sheet)) in accordance with this Agreement, ADVAXIS shall be the sponsor of (the "Sponsor") and shall conduct the Sponsored Clinical Trial at the cost and expense of ADVAXIS, and shall remain responsible for the submissions of all filings to the Regulatory Authorities to support the Sponsored Clinical Trial. ADVAXIS shall not perform the Sponsored Clinical Trial in any country other than the Territory.

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- (b) MedImmune will appoint a clinical representative for the Sponsored Clinical Trial ("MedImmune Clinical Representative"). The MedImmune Clinical Representative will receive copies of all safety reports including without limitation adverse event reports, minutes of dose escalation meetings, Study status reports, interim safety reports, as well as meeting minutes of all Investigator meetings/teleconferences. The MedImmune Clinical Representative will also have access to all clinical team correspondence including without limitation, weekly team meeting minutes, monitoring reports, site activation reports, contract status updates etc., upon request. The MedImmune Clinical Representative may participate in all investigator meetings and any audit conducting by a Regulatory Authority as described in section 3.3.5.
- (c) In addition to the Principal Investigator, ADVAXIS shall select Investigators who are qualified by their training and experience to participate in the Sponsored Clinical Trial and who have not been debarred from conducting clinical trials in the US or in any other jurisdiction in the world. ADVAXIS shall be responsible for reviewing any documentation required under Applicable Laws pertaining to an Investigator's financial interests, or any other Investigator-related requirements.
- (d) ADVAXIS shall be responsible for the negotiation and execution of the clinical trial agreements with each Study Site. The clinical trial agreements shall require the Study Sites to comply with all Applicable Laws and will contain confidentiality provisions no less stringent than those contained in this Agreement and intellectual property provisions that guarantee MedImmune rights in MedImmune Compound Inventions as provided under this Agreement. MedImmune shall have the right to review and approve the site template proposed by ADVAXIS. As between MedImmune and ADVAXIS, ADVAXIS shall be liable for all the acts and/or omissions of the Investigators and the Study Sites.

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- (e) ADVAXIS may sub-contract certain obligations to a Third Party to perform on behalf of ADVAXIS provided that ADVAXIS shall remain solely and fully liable for the performance of such subcontractors. ADVAXIS shall ensure that each of its subcontractors performs its obligations pursuant to the terms of this Agreement, including the Appendixes attached hereto. ADVAXIS shall use reasonable efforts to obtain and maintain copies of material documents relating to the obligations performed by such subcontractors that are held by or under the control of such subcontractors to be provided to MedImmune, to the extent required under this Agreement. The scope of the obligations that may be subcontracted by ADVAXIS to a Third Party may include, but shall not be limited to, aspects of work relating to Study Site contracting, clinical trial monitoring and source data verification, data management and validation, biostatistics and statistical analysis plan, and clinical study report medical writing.
- (f) ADVAXIS shall obtain Institutional Review Board ("IRB") approval or other ethics approval prior to ADVAXIS and/or any Investigators conducting any activity relating to Study Subjects (including but not limited to enrollment of Study Subjects in the Sponsored Clinical Trial) and shall conduct the Sponsored Clinical Trial in compliance with all relevant Applicable Laws and guidance governing the protection of human subjects including, without limitation, 45 C.F.R. Parts 160 and 164, patient rights to know, and use of investigational drugs (as specified at 21 C.F.R Parts 50, 56 and 312). ADVAXIS shall ensure that each Study Site has obtained from each subject prior to the commencement of any study procedures: (i) a signed informed consent form approved by the IRB or ethics committee; and (ii) authorization to disclose individually identifiable health information necessary in order to conduct the Sponsored Clinical Trial, and to provide the Study Data, analyses, and reports to MedImmune as required under this Agreement. ADVAXIS shall prepare the patient informed consent form for the Sponsored Clinical Trial in consultation with MedImmune (it being understood that the portion of the informed consent form relating to the MedImmune Development Product will be provided by MedImmune). Any changes to such form that relate to safety information regarding the MedImmune Development Product shall be subject to MedImmune's written consent, which shall not be unreasonably withheld or conditioned. MedImmune will provide such consent, or a written explanation for why such consent is being withheld or conditioned, within fifteen (15) business days of receiving ADVAXIS's request therefore. Upon MedImmune's request, ADVAXIS shall provide to MedImmune a copy of such IRB or ethics committee approval of the informed consent form and/or the master informed consent form for the Sponsored Clinical Trial. ADVAXIS shall at all times comply with any applicable data privacy legislations, regulations and guidelines applicable in any part

- (g) ADVAXIS shall be responsible for, at its own cost, packaging and labeling the ADVAXIS Development Product and MedImmune Drug Supply and shipping (including customs and taxes) the ADVAXIS Development Product and MedImmune Drug Supply (in labeled form compliant with Applicable Law) to all Study Sites that shall be performing the Sponsored Clinical Trial.
- (h) ADVAXIS shall maintain complete and accurate records relating to the disposition of the Development Products, which shall include but not be limited to: (i) details of the quantity and batch code of drug supplies delivered to each Investigator; (ii) the quantity and vial number of the vials of Development Product administered to each Study Subject; and (iii) confirmation that the Development Product are disposed of in accordance with policies of each Study Site's pharmacy (which policies shall comply with all regulatory requirements and all Applicable Laws relating to the Development Product).
- (i) ADVAXIS shall conduct a prompt investigation of any Study Site that ADVAXIS suspect to be involved in fraud and/or scientific misconduct, and ADVAXIS shall notify MedImmune within forty-eight (48) hours of the initiation of such investigation and the results of such investigation, as soon as available.
- (j) ADVAXIS will be responsible for compliance with all Applicable Law pertaining to safety reporting of the Sponsored Clinical Trial. The Parties agree that provisions relating to Adverse Event Reporting shall be set out in a separate Pharmacovigilance Agreement to ensure the exchange of relevant safety data within appropriate timeframes and in appropriate format to enable the Parties to fulfill local and international regulatory reporting obligations and to facilitate appropriate safety reviews. Both Parties shall use commercially reasonable efforts to execute the Pharmacovigilance Agreement within sixty (60) days from the Effective Date of this Agreement. The execution of the Pharmacovigilance Agreement by the Parties is a condition precedent of the implementation of the Sponsored Clinical Trial hereunder.

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- (k) The Parties agree that provisions relating to quality assurance of the Development Products shall be set out in a separate Quality Assurance Agreement. Both Parties shall use commercially reasonable efforts to execute the Quality Assurance Agreement within sixty (60) days from the Effective Date of this Agreement. The execution of the Quality Assurance Agreement by the Parties is a condition precedent of the implementation of the Sponsored Clinical Trial hereunder.
- (1) ADVAXIS shall ensure accurate and timely collection, recording, and submission of the Study Data. ADVAXIS and MedImmune shall jointly own the Study Data. During the Term, neither Party shall, without the other Party's written consent, share any Study Data from the Sponsored Clinical Trial with any third party or exploit the Study Data, except as necessary for regulatory filings and compliance with Applicable Laws. Notwithstanding the foregoing, ADVAXIS shall provide to MedImmune; and hereby grants MedImmune a limited, non-exclusive, license to (i) the Study Data in raw form and/or derived SAS datasets; and (ii) a final study report; to be used for sole purpose offor MedImmune's internal business, patent procurement and enforcement (preparing, filing, prosecuting, enforcing, or defending) of MedImmune Compound Inventions and Joint MedImmune- ADVAXIS Inventions, or legal or regulatory, or compliance purposes. On a monthly basis, no later than the 5<sup>th</sup> of each month, beginning two (2) months after first patient screened in the Sponsored Clinical Trial, ADVAXIS shall provide the MedImmune Clinical Representative with the most current Study Data in either raw form and/or derived SAS datasets as requested by MedImmune. This license is non-transferable and non-sublicensable except for Study Data directly and solely related to potential biomarker and/or diagnostics for the MedImmune Development Product, and such excepted Study Data shall be identified in writing to ADVAXIS prior to any transfer or sublicensing to a Third Party, and such Third Party must agree to reasonable terms and conditions protecting the confidentiality of such Study Data that are not less stringent than those set forth herein. ADVAXIS shall use commercially reasonable efforts to provide such Study Data and draft study report for MedImmune review and MedImmune shall provide its comments to ADVAXIS within thirty (30) days of receipt of suchdraft; provided, however, that ADVAXIS shall have the final decision as to whether incorporate any comments or changes made by MedImmune. ADVAXIS shall provide the final version of the final study report to MedImmune as soon as practicable following completion of the Sponsored Clinical Trial but in no event later than two (2) months following completion of the Sponsored Clinical Trial or termination of this Agreement. ADVAXIS shall promptly provide MedImmune with copies of any minutes or memorandums containing feedback from or communications with the FDA or any other Regulatory Authority pertaining to the MedImmune Development Product. Notwithstanding the above, MedImmune shall not be provided with study subject names or other information, which could be used for identification, or any other information proscribed by the provisions of HIPAA.

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- (i) ADVAXIS shall maintain Study reports and all related documentation in good scientific manner and in compliance with Applicable Law. On a quarterly basis, beginning three (3) months after execution of this Agreement, ADVAXIS shall provide the MedImmune Clinical Representative with interim safety and clinical data activity reports and any other information as may be reasonably requested by MedImmune as set forth in Section 3.1(b) above.
- (ii) ADVAXIS shall, in addition, provide copies of any expedited safety reports and access to any safety data as may be required pursuant to the Pharmacovigilance Agreement or as may be otherwise required by MedImmune for the purpose of any submissions to or other communications with the FDA or to any other Regulatory Authority. ADVAXIS shall respond promptly, as set forth in the Pharmacovigilance Agreement, to MedImmune's questions, comments or concerns to the safety reports and safety data provided. MedImmune acknowledges and agrees that ADVAXIS shall be responsible for registration of the Sponsored Clinical Trial and results posting as required by the FDA and by any other Regulatory Authorities, and that MedImmune shall not post or publish any Study Data, registration information or results without the prior written consent of ADVAXIS, unless required by Applicable Law, in which case MedImmune shall use reasonable efforts to provide ADVAXIS sufficient prior written notice of MedImmune's intent to post or publish any such information to allow ADVAXIS sufficient time to seek confidential treatment for such information and/or to petition to halt such posting or publication.

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- (iii) In the event that ADVAXIS reports to MedImmune an adverse event, pursuant to the Pharmacovigilance Agreement or otherwise, or any other safety data related to the ADVAXIS Sponsored Clinical Trial, which relates to the MedImmune Development Product, MedImmune shall provide all such additional information related to such MedImmune Development Product as may be reasonably required by ADVAXIS to comply with Applicable Laws. Such information may include but shall not be limited to a letter from MedImmune expressly permitting ADVAXIS to cross-reference pertinent non-clinical, clinical and chemistry manufacturing control ("CMC") information that exist under an IND in any submissions to be made by ADVAXIS to the FDA or to any other Regulatory Authority. For the avoidance of doubt, except as expressed otherwise in this clause or elsewhere in this Agreement, MedImmune shall not be required to disclose any other confidential or proprietary information related to the MedImmune Development Product in question.
- (n) In the event that the Sponsored Clinical Trial is stopped or terminated by the FDA or by any other applicable Regulatory Authority, or by an IRB or other ethics committee due to scientific or safety reasons, ADVAXIS shall promptly (within seven (7) days) inform MedImmune along with the reasons for such termination.

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- 3.2 MedImmune Obligations and Responsibilities with respect to the Sponsored Clinical Trial are as follows.
- (a) MedImmune shall allow ADVAXIS to cross-reference MedImmune's INDs or any related or corresponding regulatory filing (such as a CTA or other foreign equivalent) in the Territory for the MedImmune Development Product required for the conduct of the Sponsored Clinical Trial.
- (b) In the event that MedImmune receives adverse event information pertaining to the MedImmune Development Product, MedImmune shall promptly provide such information to ADVAXIS pursuant to the Pharmacovigilance Agreement.
- (c) MedImmune shall inform ADVAXIS of any new IND or equivalent filings in the Territory within thirty (30) days of such filing.

## 3.3 Drug Supply Availability, Forecast and Delivery

### 3.3.1

- (a) In accordance with Section 3.3.1(b) below, MedImmune shall provide the MedImmune Drug Supply, at no cost to ADVAXIS for the Sponsored Clinical Trial.
- (b) ADVAXIS shall provide MedImmune with the initial Forecast, approved by the JSC, for the Sponsored Clinical Trial at the same time as the JSC approves the protocol for the Sponsor Clinical Trial. Thereafter, ADVAXIS shall provide MedImmune, no less frequently than once every Quarter, within the first 10 (ten) Business Days of each Quarter, a Forecast, approved by the JSC, for the forthcoming twelve (12) months. Following receipt of such Forecast, MedImmune shall make the MedImmune Drug Supply available to support the Sponsored Clinical Trial based on the aforesaid Forecast provided that ADVAXIS is otherwise not in material breach of this Agreement. ADVAXIS acknowledges and agrees that MedImmune shall not be required to provide additional quantities of MedImmune Development Product on top of those quantities specified in a Forecast for the conduct of the Sponsored Clinical Trial; provided, however that, MedImmune shall use commercially reasonable efforts to provide any additional MedImmune Development Product as ADVAXIS may reasonably request to support the Sponsored Clinical Trial.

## (c) MedImmune Drug Supply Shortage.

- (i) MedImmune shall supply the MedImmune Development Product in accordance with the timelines, Forecasts and other terms of Sections 3.3.1 (a) and (b) above, except in the case of a *bona fide* supply interruption or shortage of the MedImmune Development Product, not caused by any willful acts or omissions by MedImmune ("Supply Shortage"), MedImmune shall provide ADVAXIS with prompt written notice of such Supply Shortage and the terms of Section 3.3.1(c)(ii) below shall apply.
- (ii) In the case of a Supply Shortage, MedImmune shall resume delivery of the MedImmune Development Product as soon as reasonably possible after the Supply Shortage, and the time periods set forth in this Agreement for the Sponsored Clinical Trial shall be extended by the duration of the Supply Shortage and any additional time as reasonably necessitated by the Supply Shortage or as otherwise agreed to by the Parties. During the duration of the Supply Shortage where MedImmune reasonably believes that it will not be able to supply ADVAXIS's requirements (as set forth in the Forecast) and any of its own requirements (including those of any other MedImmune licensees' and distributors), MedImmune shall provide ADVAXIS with prompt written notice thereof and, upon request, the Parties shall promptly discuss such situation and what actions has MedImmune taken to address such Supply Shortage (including but not limited to rationing, expediting, overtime, and priority transportation modes). MedImmune shall use reasonable efforts to address and resolve the Supply Shortage, but shall not be liable to ADVAXIS for failure or inability to resolve the Supply Shortage. MedImmune's reasonable efforts to address and resolve the Supply Shortage in accordance with this Section 3.3.1(c) will be ADVAXIS's exclusive remedy with respect to any Supply Shortage of the MedImmune Development Product. Notwithstanding the foregoing, both Parties acknowledge and agree that in the event MedImmune is able, using reasonable effort, to supply ADVAXIS with a reduced quantity of MedImmune's Development Product, the JSC shall determine as to how to apportion such reduced quantity within the Sponsored Clinical Trial.

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- (d) MedImmune Drug Supply Delivery. MedImmune shall package and ship unlabeled MedImmune Drug Supply for the Sponsored Clinical Trial to an ADVAXIS' location, in the timing and manner as reasonably acceptable by the Parties. MedImmune shall be responsible, at its own cost, for such packaging and shipping (including customs and taxes) of the MedImmune Drug Supply to such ADVAXIS' location only. All costs associated with the subsequent transportation, warehousing, distribution, packaging and labeling of the MedImmune Development Products shall be borne by ADVAXIS will: (i) accept delivery of the MedImmune Development Products supplied hereunder and will subsequently label, pack and promptly ship such to the Study Sites per Section 3.1(f); (ii) provide, from time to time at the reasonable request of MedImmune, any applicable chain of custody forms, in-transport temperature recorder(s) and records and receipt verification documentation; and (iii) provide such other transport documentation reasonably requested by MedImmune.
- (f) Other Supply and Quality Assurance Items. Other supply and quality items relating to the Sponsored Clinical Trials, including but not limited to, product testing, non-conformance, quality matters, changes to manufacturing, etc., are set forth in the Quality Assurance Agreement.
- **3.3.2** ADVAXIS shall not and shall ensure that its respective Investigators shall not at any time during the Term or thereafter:
  - (i) use the MedImmune Development Products for any purpose other than to conduct the Sponsored Clinical Trials in accordance with this Agreement; except as specified in this Agreement, transfer or provide access to MedImmune Development Products or their compositions, sequences or structural characteristics to any Third Party except as necessary to carry out any Sponsored Clinical Trial provided that such Third Party is also subject to the limitations of this Agreement;
  - (ii) except as specified in this Agreement, combine any MedImmune Development Products with any other materials other than the ADVAXIS Development Products;

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- (iii) except as specified in this Agreement, reverse engineer or attempt to derive the sequence, composition or structure of any of the MedImmune Development Products; or
- (iv) except as specified in this Agreement, copy, reproduce, clone, express, derive, transfect, modify, improve, purify, isolate or attempt to do any of the foregoing with respect to any of the MedImmune Development Products.
- **3.3.3** Each Party retains the sole rights to sell, offer for sale, manufacture, export, import, or otherwise commercialize their respective Development Products. The Parties shall have no obligation to advance any product indication developed from any Sponsored Clinical Trial(s) to the relevant next phase of clinical development, regulatory approval, or commercial sale.
- **3.3.4** MedImmune may at its sole expense, upon reasonable prior written notice to ADVAXIS (but no less than fifteen (15) business days), and on mutually agreed dates during normal business hours, review the facilities and procedures of ADVAXIS, Study Sites, Investigators and any other Third Party sub-contractors, directly related to the performance of the Sponsored Clinical Trial to verify compliance with Applicable Laws and with respect to any investigations carried out pursuant to Section <u>3.3.5</u> as the case may be. ADVAXIS shall use commercially reasonable efforts to properly address any non-compliance issues reported following such review, and inform the Non-Sponsor Party of the actions taken.

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- **3.3.5** ADVAXIS shall allow access to any Regulatory Authorities to inspect, observe and review the facilities and procedures of ADVAXIS Study Sites and Investigators, and manufacturing sites, directly related to the performance of any Sponsored Clinical Trial as may be required by Applicable Laws. Each Party shall allow access to any Regulatory Authorities to inspect, observe and review their facilities and procedures and any Third Party directly involved in the development, manufacture or shipping and handling of the their Development Products as the case may be, or as otherwise may be required by Applicable Laws. Each Party shall: (a) promptly notify the other Party of any such inspections and audits pertaining to the Sponsored Clinical Trial and/or the Development Products; (b) use commercially reasonable efforts to address any non-compliance issues identified by such Regulatory Authority; and (c) inform the other Party regarding the actions taken in response to such inspection or audit.
- **3.3.6** Except with respect to the Sponsored Clinical Trial in accordance with this Agreement, ADVAXIS shall not research, develop, or perform a clinical trial or negotiate with or grant to a third party such rights with respect to a combination regimen of both: (i) ADVAXIS Development Product and (ii) PD-1 Antibody and/or PD- L1 Antibody (including but not limited to MedImmune Development Product). The obligations under this Section <u>3.3.6</u> shall not survive termination or expiration of this Agreement.
- **3.3.7** The Parties agree that each Party shall be responsible for any and all taxes of whatever nature (including related fines, penalties, surcharges of interest) ("*Tax*" or "*Taxes*") imposed or payable to any authority, body or official anywhere in the world imposed on such Party by virtue of their performance under this Agreement. In addition,

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- (a) Each Party shall be responsible for Taxes imposed or calculated by reference to net income or profit, employees employed by that party, assets in which it has an interest, gross income or its equity or share capital. Further each Party shall be responsible for Taxes imposed or calculated on transactions within the Party and its Affiliates, whether in respect of this Agreement or otherwise.
- (b) The Parties shall reasonably work together with respect to audits, disputes or requests for information with respect to Taxes (e.g. provision of relevant information and documents) in connection with this Agreement.
- **3.3.8** The Parties shall cooperate to ensure that the Party responsible for shipped goods in accordance with Applicable Laws maximizes the full benefits of available duty free or savings programs and minimizes where permissible any such duties and any related import taxes that are not reclaimable from the relevant authorities. The shipping Party shall be responsible for any import clearance, including payment of any import duties and similar charges, in connection with any shipped goods under this Agreement.
- **3.3.9** ADVAXIS shall ensure that each Study Site clinical trial agreement and patient consent forms signed by the Study Subjects allows for access to and use of Samples such that the Parties are able to conduct analysis and assays on the Samples as specified in the Protocol Concept Sheet. The initial agreement of the Parties regarding such Samples analysis is attached hereto as Appendix B, the Samples Analysis/Assays Procedures. This analysis plan may be amended from time to time as agreed by the JSC. Subject to JSC approval and the appropriate consent given by Study Subjects in the signed patient consent forms and Applicable Law, and only after sufficient quantities of Samples are available to support the analysis in Appendix B, each Party shall have access to use Samples to conduct research that exceeds or differs from the research specified in the final protocol approved by the JSC, including genetic research ("Secondary Research") for purposes outside the scope of this Agreement. MedImmune shall own all Sample analysis or research results conducted by or on behalf of MedImmune and shall have no obligation to disclose or share such results with ADVAXIS shall ensure that any collection, handling, transportation and retention of any Samples, is carried out in accordance with the final protocol approved by the JSC, informed consent and Applicable Laws. Each party shall ensure that the security, integrity and quality of the Samples, whether in their possession or the possession of a third party on their behalf, are maintained at all times.

## 3.4 Negotiation of a Clinical Development and Commercialization Agreement

- **3.4.1** During the Negotiation Period, ADVAXIS and MedImmune shall meet, discuss and negotiate in good faith in an attempt to enter into an agreement with respect to the development, regulatory approval, and commercialization of a MedImmune Development Product and ADVAXIS Development Product to be used in conjunction with each other for the treatment or prevention of cancer (the "Clinical Development and Commercialization Agreement"). Neither Party shall be obligated to enter into such Clinical Development and Commercialization Agreement, and neither Party shall be liable to the other Party for failure to enter into such Clinical Development and Commercialization Agreement.
- **3.4.2** In the event that MedImmune and ADVAXIS do not enter into a Clinical Development and Commercialization Agreement during the Negotiation Period, and ADVAXIS, its Affiliate, collaborator, licensee or sub-licensee obtains Regulatory Approval of ADVAXIS Development Product or its Derivative or Progeny for use in combination with any PD-1 Antibody or PD-L1 Antibody, ADVAXIS shall pay MedImmune [c.i.] within thirty (30) days after such Regulatory Approval, and a Royalty of [c.i.], which royalty shall be payable on a Royalty Bearing Product by Royalty Bearing Product basis for a period of ten (10) years from the first commercial sale of the applicable Royalty Bearing Product. With respect to such Royalty Bearing Product, ADVAXIS shall continue to make payments for such period of time that MedImmune has not brought suit or a claim of action, or is assisting or participating in a third party suit or claim of action against ADVAXIS under MedImmune's rights in the Joint-MedImmune-ADVAXIS Inventions.
- **3.4.3** In the event MedImmune and ADVAXIS do not enter into a Clinical Development and Commercialization Agreement, upon expiration of the Term, neither Party shall share any Study Data or results with third parties (except as necessary for regulatory filings and compliance with Applicable Laws), including without limitation to current collaboration partners, except in summarized form. If a Party desires to share summarized Study Data with third parties, the summary may show that Party's Development Product's dose and schedule (but not the other Party's Development Product's dose and schedule). Any proposed sharing shall be subject to review and approval by the other Party, not to be unreasonably withheld, provided that the summarized form of the Study Data does not contain any Study Data specific to the Other Party's Development Product. The disclosing Party shall submit such summarized Study Data for review by the other Party at least sixty (60) days prior to any proposed disclosure to third parties.

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## 4. INTELLECTUAL PROPERTY RIGHTS.

**4.1** Except as expressly set forth in this Agreement, no Intellectual Property Rights of a Party shall be granted to any other Party, by implication, estoppel or otherwise. All rights in and to a Party's Background Intellectual Property shall be reserved to and individually retained by the Party who owns such Background Intellectual Property. Inventorship of Inventions, whether patentable or not, shall be determined in accordance with United States patent laws.

**4.2** All Intellectual Property Rights (including but not limited to new patentable and non-patentable inventions) made, conceived, reduced to practice and/or generated through the conduct of the Sponsored Clinical Trials, whether created solely by MedImmune Representatives or solely by ADVAXIS Representatives or jointly by MedImmune Representatives and ADVAXIS Representatives, that relate solely to one or more MedImmune Development Products (or to any Third Party product or material that MedImmune uses in the conduct of a Sponsored Clinical Trial) shall be owned solely by MedImmune ("MedImmune Compound Invention"). For clarity, MedImmune Compound Inventions (whether patentable or not) that relate solely to the MedImmune Development Products shall include those that generically encompass a MedImmune Development Product (and not the ADVAXIS Development Product nor any other Intellectual Property of ADVAXIS or its Affiliates either existing as of the Effective Date of this Agreement or are, or have been, developed without reliance on a MedImmune Development Product) within its scope, even where such MedImmune Development Product is not disclosed per se, as well as biomarkers. ADVAXIS shall promptly notify MedImmune upon the making, conception, reduction to practice and/or generation of any such MedImmune Compound Invention and hereby assign all rights, title and interest in the aforesaid to MedImmune, and agrees to execute any additional documents necessary to enable such assignment to MedImmune.

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**4.3** All Intellectual Property Rights (including but not limited to new patentable and non-patentable inventions) made, conceived, reduced to practice and/or generated through the conduct of the Sponsored Clinical Trials, whether created solely by MedImmune Representatives or solely by ADVAXIS Representatives or jointly by MedImmune Representatives and ADVAXIS Representatives, which relate solely to one or more ADVAXIS Development Products shall be owned solely by ADVAXIS ("**ADVAXIS Invention**"). For clarity, ADVAXIS Inventions (whether patentable or not) that relate solely to the ADVAXIS Development Product shall include those that generically encompass an ADVAXIS Development Product (and not the MedImmune Development Product nor any other Intellectual Property of MedImmune or its Affiliates either existing as of the Effective Date of this Agreement or are, or have been, developed without reliance upon a ADVAXIS Development Product) within its scope, even where such ADVAXIS Development Product is not disclosed per se,. MedImmune shall promptly notify ADVAXIS upon the making, conception, reduction to practice and/or generation of any such ADVAXIS Invention and hereby assign all rights, title and interest in the aforesaid to ADVAXIS, and agrees to execute any additional documents necessary to enable such assignment to ADVAXIS.

**4.4** Subject to Section <u>4.5</u> below, all Intellectual Property Rights (including but not limited to new patentable and non-patentable inventions) made, conceived, reduced to practice and/or generated through the conduct of the Sponsored Clinical Trials, whether created solely by MedImmune Representatives or solely by ADVAXIS Representatives or jointly by MedImmune Representatives and ADVAXIS Representatives, which relate to the combination of one or more MedImmune Development Product and one or more ADVAXIS Development Products shall be jointly owned by MedImmune and ADVAXIS ("Joint MedImmune-ADVAXIS Invention"). MedImmune or ADVAXIS (each the "Discovering Party"), as the case may be, shall promptly notify the other Party upon the making, conception, reduction to practice and/or generation of any Joint MedImmune- ADVAXIS Invention.

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- 4.4.1 In the event the Parties do not enter into a Clinical Development and Commercialization Agreement, ADVAXIS covenants and agrees not to exploit, commercialize or license the Joint MedImmune-ADVAXIS Inventions except as for the performance of obligations under the Agreement. If ADVAXIS desires to exploit, commercialize or license the Joint MedImmune-ADVAXIS Inventions, it may negotiate and obtain from MedImmune a license to do so. In the event that ADVAXIS desires such a license, ADVAXIS shall notify MedImmune and MedImmune and ADVAXIS shall negotiate such a license in good faith under reasonable commercial terms; provided, however, that MedImmune shall not be obligated to grant such a license and shall not be held liable to ADVAXIS for failure to grant such a license.
- 4.4.2 MedImmune shall not be prevented from or require prior approval from ADVAXIS to exploit, commercialize or license the Joint MedImmune-ADVAXIS Inventions.

4.5

(a) MedImmune shall have the sole right to prepare, file, prosecute, maintain, enforce and defend all U.S. and foreign Patents and other forms of Intellectual Property Rights, using patent counsel of its choice, covering all MedImmune Compound Inventions.

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- (b) ADVAXIS shall have the sole right to prepare, file, prosecute, maintain, enforce and defend all U.S. and foreign Patents and other forms of Intellectual Property Rights, using patent counsel of its choice, covering all ADVAXIS Compound Inventions.
- (c) MedImmune shall have the sole right to prepare, file, prosecute, maintain, enforce and defend all U.S. and foreign Patents and other forms of Intellectual Property Rights, using patent counsel of its choice, covering all Joint MedImmune-ADVAXIS Inventions. All costs associated with preparing, filing, prosecuting, maintaining, enforcing, and defending all jointly owned Joint MedImmune-ADVAXIS Inventions shall be shared by the Parties. In the event that MedImmune does not exercise such rights, MedImmune shall notify ADVAXIS, and in such event, ADVAXIS shall have the sole right to copy, prepare, prosecute and maintain such joint MedImmune-ADVAXIS Inventions.
- (i) Each Party shall contact the other as soon as possible after identifying any information, including but not limited to a future publication, competitive intelligence, or any public disclosure, that would require filing a Joint MedImmune-ADVAXIS Invention application.
- (ii) In the event MedImmune decides not to pursue or decides to abandon any Joint MedImmune-ADVAXIS Invention application or patent, ADVAXIS shall have the right at, its own expense, to take control of the prosecution and enforcement of such an application or patent.
- (d) Each Party agrees to reasonably cooperate with the other Party to execute all lawful papers and instruments, including obtaining and executing necessary powers of attorney and assignments by the named inventors, to make all rightful oaths and declarations, and to provide consultation and assistance as may be reasonably necessary in the prosecution, maintenance and enforcement of all ADVAXIS Compound Inventions, Joint MedImmune- ADVAXIS Inventions, and MedImmune Compound Inventions undertaken in a manner consistent with this Section 4. Nothing in this Section 4.5(d) with regard to cooperation shall require either Party to make statements or take other action that could be adverse to or to the detriment of the prosecution, maintenance, enforcement or defense of its own Compound Inventions or Background Intellectual Property.

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**4.6** MedImmune and ADVAXIS, as the case may be, shall keep the other party reasonably informed of the status of the prosecution of MedImmune-Advaxis Inventions by providing information relating to any substantive decisions taken by the applicable party relating to patent examination and maintenance.

**4.7** Each Party shall promptly notify the other Party in writing of any allegation by a Third Party that the activity of either of the Parties pursuant to this Agreement infringes or may infringe the intellectual property rights of such Third Party. ADVAXIS shall have the first right to control any defense of any such claim at its own expense and by counsel of its own choice if the intellectual property rights of such Third Party concern a ADVAXIS Development Product. MedImmune shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Likewise, MedImmune shall have the first right to control any defense of any such claim at its own expense and by counsel of its own choice if the intellectual property rights of such Third Party concern a MedImmune Development Product. ADVAXIS shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Neither Party shall have the right to settle any patent infringement litigation under this Section 4.7 in a manner that diminishes the rights or interest of the other Party without the prior written consent of such other Party.

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## 5. CONFIDENTIAL INFORMATION, PUBLICITY AND PUBLICATION.

- **5.1 Nondisclosure Obligations**. Each Receiving Party shall use the Confidential Information of a Disclosing Party only in accordance with the activities contemplated by this Agreement and shall not disclose to any third party such Confidential Information without the prior written consent of the Disclosing Party or as expressly provided below. A Receiving Party shall use the same degree of care with respect to a Disclosing Party's Confidential Information that it uses with respect to its own Confidential Information and shall only disclose such information on a need-to-know basis to individuals who are under a written obligation of confidentiality, or are otherwise so obligated. Each Party's obligations of non-disclosure and non-use shall continue with respect to Confidential Information disclosed to it by the Disclosing Party for a period of ten (10) years from the date of the initial disclosure to the Receiving Party of each such item of Confidential Information. These obligations shall not apply to Confidential Information that is:
  - (a) known by a Receiving Party at the time of receipt and not through a prior disclosure by a Disclosing Party to the Receiving Party, as documented by business records:
  - (b) at the time of disclosure or thereafter becomes published or otherwise part of the public domain without breach of the Agreement by a Receiving Party;
  - (c) subsequently disclosed to a Receiving Party by a third party who Receiving Party reasonably believes has the right to make such disclosure;
  - (d) developed by a Receiving Party independently of Confidential Information received from a Disclosing Party and such independent development can be properly demonstrated by the Receiving Party; or
  - (e) not identified as proprietary information in writing and appropriately marked at the time it is disclosed by a Disclosing Party to a Receiving Party.
- **5.2 Permitted Disclosures.** Notwithstanding the provisions of Section <u>5.1</u>, a Receiving Party may disclose Confidential Information to the extent required to comply with applicable law, governmental regulation, subpoena or court order, provided that notice is promptly delivered to a Disclosing Party, where legally permitted, in order to provide it with an opportunity to seek a protective order or other similar order with respect to such Confidential Information and the Receiving Party thereafter discloses only the minimum information reasonably required to be disclosed in order to comply with the request, whether or not a protective order or other similar order is obtained by the Disclosing Party.
- **5.3 Partial Disclosures.** Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of a Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of such Party. Further, any combination of individual elements of Confidential Information shall not be considered in the public domain or in the possession of a Party merely because one or more individual elements of such Confidential Information are in the public domain or in the possession of such Party unless every feature of the Confidential Information that has been disclosed in accordance with the provisions herein is disclosed in the combination.

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**5.4 Publicity.** Each Party agrees that, except as required by Applicable Laws or regulations, it shall not, without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed, use the name of the other Party in any advertising, promotional or publicity material, or make any form of representation or statement in relation to the Sponsored Clinical Trials, which would constitute an express or implied endorsement by the other Party.

**5.5 Return or Destruction of Confidential Information.** At any time after expiration or termination of this Agreement, a Disclosing Party may notify a Receiving Party in writing that such Receiving Party must destroy or return to the Disclosing Party the Disclosing Party's Confidential Information. Each Receiving Party hereby agrees to, within thirty (30) days of such notification: (a) return all documents and tangible items it or its employees or agents have received or created pursuant to this Agreement pertaining, referring or relating to the other Party's Confidential Information; and (b) return or certify (in a writing attested to by a duly authorized officer of such Party) destruction of all copies, summaries, modifications or adaptations that such Party or its employees or agents have made from the materials provided by the Disclosing Party; provided, however, that a Party is permitted to retain one copy of such materials in its legal files to be used to verify compliance with its obligations hereunder and provided that neither the Receiving Party nor any of its Affiliates shall be required to delete or destroy any electronic back-up tapes or other electronic back-up files that have been created solely by their automatic or routine archiving and back-up procedures, to the extent created and retained in a manner consistent with its or their standard archiving and back-up procedures.

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- **5.6 Publication.** Both Parties acknowledge and agree that neither Party shall have the right to submit Study Data for publication or presentation or any other dissemination, either orally or in writing (a "*Publication*") prior to expiration of the Negotiation Period, except in the event of required securities filings with the SEC (or its equivalent foreign agency) and only after complying with the procedure for such disclosure in Section <u>5.2 above</u>. Prior to Publication, the publishing Party shall allow the other to comment on the content of the Publication to be published or presented according to the following procedure:
- (i) At least sixty (60) days prior to submission for Publication of any paper, letter, abstract, poster, talk or any other presentation or publication, the publishing Party shall provide to the other Party details of the proposed Publication in an electronic version (cd-rom or email attachment). Upon written request from the other Party, the publishing Party agrees not to submit data for Publication for sixty (60) days in order to allow for actions to be taken to preserve rights for patent protection.
- (ii) The publishing Party shall give reasonable consideration to any request by the other Party made within the periods mentioned in clause (i) above to modify the Publication.
  - (iii) The publishing Party shall remove all Confidential Information of the other Party before finalizing the Publication.

Each such Publication shall appropriately acknowledge both Parties, as applicable, for their participation in and contribution to the particular Sponsored Clinical Trial.

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## 6. TERM AND TERMINATION.

**6.1 Term.** This Agreement shall take effect as of the Effective Date and shall remain in effect until the earlier of (i) permitted termination of this Agreement (ii) the Parties entering into a Clinical Development and Commercialization Agreement pursuant to Section 3.4 or expiration of the Negotiation Period (*"Term"*), unless the Parties mutually agree to an extension of the Term, prior to the expiration of the Term by agreement, in writing; provided, however, this Agreement shall remain in effect beyond the Term with respect to rights and obligations that survive termination of this Agreement.

## 6.2 Termination.

- (a) Either Party may terminate this Agreement upon thirty (30) days' written notice to the other Party if the other Party commits a material breach of this Agreement, unless such breach is cured within the thirty (30) day notice period, or if such breach is not capable of being cured within thirty (30) days if, during such thirty (30) day period, the breaching Party initiates actions reasonably expected to cure the breach and thereafter diligently proceeds to cure the breach.
- (b) The Parties acknowledge that patient safety is of the ultimate concern and importance. Either Party may terminate this Agreement immediately upon written notice to the other Party if the terminating Party determines in good faith, based on a review of the Study Data or other Study-related information, that the Study may unreasonably affect the Study Subjects' safety.

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- (c) Either Party shall have the right to terminate this Agreement immediately upon notice in the event that it learns of any debarment of the other Party and/or any of its Representatives pursuant to Section 11, and/or in the event that it becomes aware of any fraud or scientific misconduct on the part of the other Party and/or any of their Representatives.
- (e) Either Party shall have the right to terminate this Agreement upon written notice to the other Party (i) if voluntary or involuntary proceedings by or against the other Party are instituted in bankruptcy or under any insolvency law, or a receiver or custodian is appointed for the other Party, or proceedings are instituted by or against the other Party for the dissolution or liquidation of the other Party under the U.S. Bankruptcy Code, which proceedings, if involuntary, shall not have been dismissed within ninety (90) days after the date of filing, or if the other party makes an assignment for the benefit of creditors, or substantially all of the assets of the other party are seized or attached and not released within ninety (90) days thereafter, or (ii) upon the voluntary liquidation, dissolution, winding up or cessation of business by the other Party other than in connection with a permitted assignment of this Agreement
- (f) Either Party may terminate this Agreement immediately upon written notice to the other Party in the event that any Regulatory Authority takes any action, or raises any objection, that permanently prevents the terminating Party from supplying its Development Product for purposes of the Sponsored Clinical Trial. If supply of the Development Product will be delayed (but not permanently prevented) due to such Regulatory Authority action, the Parties shall mutually agree in good faith as to the appropriate course of action. Additionally, either Party shall have the right to terminate this Agreement immediately upon written notice to the other Party in the event that it determines, in its sole discretion, to permanently discontinue development of its Development Product, for medical, scientific or legal reasons.
- (g) Either Party shall be entitled to terminate this Agreement immediately upon written notice to the other Party, if such other Party fails to perform its obligations in accordance with Section 12, and such failure to perform is not cured within ten (10) business days after receipt of written notice specifying the nature of such breach. The other Party shall have no claim against the terminating Party for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this Section 6.2(g). To the extent (and only to the extent) that the laws of the Territory provide for any such compensation to be paid to the other Party upon the termination of this Agreement, the other Party hereby expressly agrees (to the extent possible under the laws of the territory) to waive or to repay to the Party terminating this Agreement any such compensation or indemnity.

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## 6.3 Consequences of Termination.

- (a) Upon termination (including expiration) of this Agreement for any reason: (i) MedImmune and/or ADVAXIS shall terminate all tasks (if any) relating to the Sponsored Clinical Trial subject to this Agreement in an orderly manner, as soon as practical, and in accordance with a schedule to be agreed to by the Parties within thirty (30) days, subject to the rights and obligations of ADVAXIS or its Investigators to complete such clinical trial(s) and ensure patient safety, and in accordance with Section 6.4; (ii) ADVAXIS shall provide to MedImmune a copy of all Study Data generated up until the date of termination or expiry of the Agreement; (iii) the Parties shall either return or destroy copies of all materials required to be exchanged pursuant to this Agreement, at the request of the Party who supplied such materials; (iv) MedImmune shall have no further obligations to make available its Drug Supply and any Drug Supply in the possession of ADVAXIS or Investigators shall either be returned to MedImmune or destroyed, at MedImmune's request; and (v) the Parties shall pay any monies, if any, due and owed up to the time of termination as required by this Agreement or any other agreement.
- (b) Nothing herein shall be construed to release either Party of any obligation pursuant to this Agreement for which the principal basis occurred prior to the effective date of any termination.
- (c) The expiration or earlier termination of this Agreement shall not relieve the Parties from performing any obligations accrued prior to the date this Agreement expires or terminates. Without limitation to the foregoing, and to any other Sections of this Agreement which are expressly stated to survive termination or expiry of this Agreement, or which need to survive to accomplish the purpose of the provision, the Parties expressly agree that Sections 3.3.6, 3.4.2, 3.4.3, 4, 5, 6.3, 6.4, 7 and 8 shall survive any termination or expiration of this Agreement.

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**6.4 Wind-down.** MedImmune and ADVAXIS recognize that early termination of this Agreement requires both discussion and coordination between the Parties to ensure patient safety, continuity of treatment, if appropriate, and compliance with Applicable Laws. Upon early termination of this Agreement for any reason, the Parties shall cooperate to provide for an orderly cessation of the Sponsored Clinical Trial, which shall take place by such time period following the date of termination as has been mutually agreed by the Parties. Each Party further agrees to take no action or forego taking action if such action or forbearance would in any manner jeopardize patient safety or the utility, quality or integrity of the Sponsored Clinical Trial, or the associated Study Data, or violate or cause the other Party to violate any Applicable Laws. In addition, ADVAXIS shall conduct such activities as are reasonably necessary in connection with the orderly wind-down of the Sponsored Clinical Trial in question.

# 7. REPRESENTATIONS AND WARRANTIES.

**7.1 Authorization.** Each Party hereby represents and warrants to the other Party that: (a) it duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation; (b) has all requisite power and authority to execute, deliver and perform this Agreement and to consummate the transactions contemplated hereby; (c) this Agreement has been duly authorized, executed and delivered by such Party, constitutes a legal, valid and binding obligation of such Party and is enforceable against such party in accordance with its terms; and (d) it is under no contractual or other obligation or restriction that is inconsistent with its execution or performance of this Agreement.

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## 7.2 MedImmune Representations and Warranties. MedImmune represents and warrants that:

- (a) MedImmune has not granted rights, and shall not grant rights, to any Third Party that conflict with the rights granted to ADVAXIS pursuant to Section 4.
- (b) MedImmune Drug Supply shall meet the standards for Good Manufacturing Practice and comply with all Applicable Laws.
- (c) The MedImmune Development Product is the property of MedImmune and the use by ADVAXIS, Study Sites or Investigators of MedImmune Development Products does not and will not infringe any Intellectual Property Rights of any Third Party.

# **7.3 ADVAXIS Representations and Warranties.** ADVAXIS represents and warrants that:

- (a) ADVAXIS has not granted rights, and shall not grant rights, to any Third Party that conflict with the rights granted to MedImmune pursuant to Section 4.
- (b) ADVAXIS shall perform the Sponsored Clinical Trial in accordance with Applicable Laws.
- (c) ADVAXIS has or will have the rights to conduct the Sponsored Clinical Trial and to grant the rights arising from such Sponsored Clinical Trials in accordance with Sections 3 and 4.
- (d) ADVAXIS has all rights in and to the ADVAXIS Development Product and the use by ADVAXIS, the Study Sites or Investigators of ADVAXIS Development Products does not and will not infringe any Intellectual Property Rights of any Third Party.

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**7.4 Compliance with Laws.** Each Party hereby represents and warrants that it will perform its obligations under this Agreement in a professional manner and in accordance with Applicable Laws.

**7.5 Warranty Disclaimer.** SECTIONS 7.1 - 7.4 SET FORTH THE ONLY WARRANTIES PROVIDED BY ANY PARTY CONCERNING THIS AGREEMENT and the transactions contemplated hereby. THESE WARRANTIES, TOGETHER WITH THE INDEMNIFICATION UNDERTAKINGS OF SECTION <u>8.3</u>, ARE MADE EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY, NON-INFRINGEMENT, TITLE OR OTHERWISE.

# 8. REMEDIES; RISK ALLOCATION.

**8.1 Equitable Remedies.** The Parties acknowledge and agree that, in the event of a breach or a threatened breach of Sections <u>4 and 5</u> of this Agreement, a Party may suffer irreparable damage (in addition to financial harm) for which it will have no adequate remedy at law and, accordingly, a Party shall be entitled to injunctive and other equitable remedies to prevent or restrain, temporarily or permanently, such breach or threatened breach, without the necessity of posting any bond or surety. Such remedies shall be in addition to any other remedy that such Party may have at law or in equity.

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## 8.2 Limitation of Liability.

- (a) Except AS OTHERWISE PROVIDED IN section <u>8.3</u> WITH RESPECT TO third party claims, IN NO EVENT SHALL either party be liable TO THE OTHER OR TO ANY THIRD PARTY for any LOST PROFITS OR SAVINGS OR FOR ANY indirect, incidental, consequential, special, PUNITIVE or exemplary damages IN CONNECTION WITH THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT, however caused, under any theory of liability, REGARDLESS OF WHETHER THE PARTIES HAVE ADVISED OR BEEN ADVISED OF THE POSSIBILITY OF ANY SUCH LOSS OR DAMAGE.
- (b) The disclaimers, limitations and exclusions set forth in this Agreement were specifically negotiated by the Parties and form an essential basis for the terms and conditions contained in this Agreement.

## 8.3 Indemnification.

(a) ADVAXIS shall defend, indemnify, and hold harmless MedImmune and their Affiliates, officers, directors, employees, and their successors and assigns (each, in such capacity, a "MedImmune Indemnitee") from and against any claim, suit, demand, loss, damage, expense (including reasonable attorneys' fees of MedImmune Indemnified Party(ies) and those that may be asserted by a Third Party) or liability (collectively, "Losses") arising from any claim or proceeding against the MedImmune Indemnitee by a Third Party to the extent that such claim or proceeding is based on: (i) any claim of infringement of patent rights with respect to the ADVAXIS Development Products; (ii) breach of any ADVAXIS representations and warranties under this Agreement; or (iii) product liability or personal injury (including, but not limited to, actions in the form of tort, warranty, or strict liability) arising from or relating to the Sponsored Clinical Trial or the development, testing, manufacture, commercialization, use or other disposition of any ADVAXIS Development Product (except that this Section 8.3(a)(iii) shall not apply to any negligence, gross negligence or willful misconduct by any of the MedImmune Indemnitees or their agents; to any activities conducted by any of the MedImmune Indemnitees outside the scope of this Agreement; to any violation by any of the MedImmune Indemnitees or their agents of any Applicable Laws; or to any unauthorized representations or warranties relating to the ADVAXIS Development Product made by any of the MedImmune Indemnitees or their agents).

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- (b) MedImmune shall defend, indemnify, and hold harmless ADVAXIS and its Affiliates, officers, directors, employees, agents, and their successors and assigns (each, in such capacity, an "ADVAXIS Indemnitee") from and against any Losses arising from any claim or proceeding against the ADVAXIS Indemnitee by a Third Party to the extent that such claim or proceeding is based on: (i) any claim of infringement of patent rights with respect to the MedImmune Development Products, (ii) breach of any of MedImmune representations and warranties under this Agreement; or (iii) product liability or personal injury (including, but not limited to, actions in the form of tort, warranty, or strict liability) arising from or relating to the development, testing, manufacture, commercialization, use or other disposition of the MedImmune Development Product (except that this Section 8.3(b)(iii) shall not apply to any negligence, gross negligence or willful misconduct by any of the ADVAXIS Indemnitees or their agents; to any activities conducted by any of the ADVAXIS Indemnitees outside the scope of this Agreement; to any violation by any of the ADVAXIS Indemnitees or their agents of any Applicable Laws; or to any unauthorized representations or warranties relating to the MedImmune Development Product made by any of the ADVAXIS Indemnitees or their agents).
- **8.4** Terms of Indemnification. If any claim is made by a third party against a ADVAXIS Indemnitee or a MedImmune Indemnitee ("Indemnitee"), such Party shall be defended, at the indemnifying Party's sole expense, by counsel selected by the indemnifying Party and reasonably acceptable to the Indemnitee, provided that the Indemnitee may, at its own expense, also be represented by counsel of its own choosing. The indemnifying Party shall have the sole right to control the defense of any such claim or action, subject to the terms of this Section <u>8.4</u> including:
  - (a) The indemnifying Party's indemnification under Section <u>8.3</u> shall not apply to any claim determined by final judgment to be attributable to the negligence, gross negligence, intentional misconduct or unlawful act of any Indemnitee.
  - (b) The indemnifying Party may settle any such claim, demand, action or other proceeding or otherwise consent to an adverse judgment (i) with prior written notice to the Indemnitee but without the consent of the Indemnitee if the only liability of the indemnifying Party to the Indemnitee is the payment of money and the indemnifying Party makes such payment or (ii) in all other cases, only with the prior written consent of the Indemnitee, given that such consent shall not to be unreasonably withheld, delayed or conditioned.

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(c) The Indemnitee shall notify the indemnifying Party promptly of any claim, demand, action or other proceeding for which it seeks indemnification hereunder within fifteen (15) business days of receipt of any such claim, demand action or other proceeding. The Indemnitee shall not settle or otherwise consent to an adverse judgment in any such claim, demand action or other proceeding or make any admission as to liability or fault without the express written permission of the indemnifying party, unless Indemnitee first releases indemnifying Party from its obligations hereunder.

**8.5 Insurance.** Each Party shall have and maintain in effect insurance coverage of commercial general liability which is adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated. Such insurance shall be endorsed to include commercial general liability insurance of not less than two million US dollars (U.S. \$2,000,000) per occurrence and not less than five million US dollars (U.S. \$5,000,000) in aggregate. Each Party shall provide the other Party with a certificate of insurance upon request. Each Party shall provide the other Party with at least fifteen (15) business days prior written notice of any material change, cancellation or expiration of the above-required insurance. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Section 8. Each Party shall have the right to satisfy this requirement through a program of self-insurance.

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## 9. RECORDKEEPING; REGULATORY ASSISTANCE.

## 9.1 Recordkeeping.

- 9.1.1 ADVAXIS will prepare and maintain, and require each Investigator for the Sponsored Clinical Trial to prepare and maintain, complete, current, accurate, organized and legible study records in a manner acceptable for the collection of data for submission to, or review by, the FDA or other applicable Regulatory Authorities and in full compliance with any protocols and any Applicable Law.
- 9.1.2 ADVAXIS will prepare and maintain complete, current, accurate, organized and legible records pertaining to the manufacture, labeling and shipping of the ADVAXIS Development Products for submission to, or review by, the FDA or other applicable Regulatory Authorities and in full compliance with any protocols and any Applicable Law. MedImmune will prepare and maintain complete, current, accurate, organized and legible records pertaining to the manufacture and shipping of the MedImmune Development Products for submission to, or review by, the FDA or other applicable Regulatory Authorities and in full compliance with any protocols and any Applicable Law.
- 9.2 ADVAXIS shall retain, or require Study Sites, Investigators, or other Representatives to retain, all study records during the Sponsored Clinical Trial and thereafter until the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region (the "Retention Period"). At the end of the Retention Period, ADVAXIS may retain or destroy, in ADVAXIS's sole discretion, such study records.

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## 10. DISPUTE RESOLUTION.

The Parties will attempt to settle any claim or controversy arising out of this Agreement or the subject matter hereof through consultation and negotiation in good faith in a spirit of mutual cooperation. If the individuals who normally handle the day-to-day matters pertaining to this Agreement are not able to resolve such dispute, such matters will be elevated to individuals of each Party at the Vice President level or higher, who shall use reasonable efforts to attempt to resolve the dispute through good faith negotiations by telephone or in person as may be agreed. If they fail to resolve the dispute within thirty (30) days after it is referred to them and do not mutually agree to extend the time for negotiation, then either Party shall have the right to pursue any judicial remedy at law or in equity. Notwithstanding the foregoing, either Party may immediately pursue judicial remedies for disputes pertaining to potential breaches of Sections 4.1-4.5 or 5 of this Agreement in order to preserve such Party's Intellectual Property Rights and Confidential Information.

# 11. DEBARMENT.

Each Party hereby certifies that neither it nor any of its Representatives has been debarred, or been convicted of a crime which could lead to debarment, under the US Generic Drug Enforcement Act of 1992 or similar laws under any other jurisdiction. If a Party or any of its Representatives is debarred or receives notice of an action or threat of action of debarment, such Party shall immediately notify the other Party of same. Each Party understands that receipt of such notice may result in the immediate termination of this Agreement.

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## 12. ANTI-BRIBERY AND ANTI-CORRUPTION.

Each Party agrees, on behalf of itself and its officers, directors, employees, Affiliates, agents and Representatives, that, in connection with the matters that are the subject of this Agreement, and the performance of its obligations hereunder:

- (a) it will comply with the Anti-bribery and Anti-corruption Laws and the Anti-Corruption Policies, and will not take any action that will cause the other Party or its Affiliates to be in violation of any such laws or policies.
- (b) it will not, directly or indirectly, pay, offer or promise to pay, or authorize the payment of any money, or give, offer or promise to give or authorize the giving of anything of value to:
  - (i) any Government Official in order to influence official action;
  - (ii) any person (whether or not a Government Official) (A) to influence that person to act in breach of a duty of good faith, impartiality or trust ("acting improperly"), (B) to reward the person for acting improperly, or (C) where that person would be acting improperly by receiving the thing of value; or
  - (iii) any other person while knowing or having reason to know that all or any portion of the money or thing of value will be offered, promised or given to a Government Official in order to influence official action or to any person to influence that person to act improperly.
- (c) It will not directly or indirectly solicit, receive or agree to accept any payment or anything else of value in violation of the Anti-Corruption Laws or the Anti-Corruption Policies.

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## 13. GENERAL.

- **13.1 Independent Contractors.** This Agreement and the relations hereby established by and among ADVAXIS and MedImmune does not constitute a partnership, joint venture, franchise, agency or contract of employment. Neither Party is granted, and neither Party shall exercise, the right or authority to assume or create any obligation or responsibility on behalf of or in the name of any other Party or such Party's Affiliates.
- **13.2 Force Majeure.** Except as otherwise provided in this Agreement, in the event that a delay or failure of a Party to comply with any obligation created by this Agreement is caused by acts of God, wars, revolution, civil commotion, acts of public enemy, labor strikes (other than employees of the affected party), terrorism, embargo or acts of government in its sovereign capacity (*"Force Majeure"*), the "affected Party" will, after giving prompt notice to the "disadvantaged Party(ies)," be excused from such performance on a day-to-day basis during the continuance of such prevention, restriction, or interference (and the disadvantaged Party(ies) will likewise be excused from performance of its obligations on a day-to-day basis during the same period), provided, however, that the affected Party will use its best efforts to avoid or remove the causes of nonperformance and all Parties will proceed immediately with the performance of their obligations under this Agreement whenever the causes are removed or cease.
- 13.3 This Agreement and the rights and obligations under this Agreement may not be assigned by operation of law or otherwise by either Party without the consent of the other Party, *provided*, *however*, that either Party may assign this Agreement without the consent of the other Party to an Affiliate or to a successor by virtue of a sale of all or substantially all of its assets related to this Agreement, merger, consolidation or similar transaction provided, further, that the assigning Party shall deliver written notice of any such permitted assignment to the other Party, and the assignee shall agree to be bound to the non-assigning Party under the terms and conditions of this Agreement. Subject to the restriction on assignment of this Section 13.3, this Agreement shall be binding upon and inure to the benefit of the successors and assigns of the Parties. Any purported assignment that is not in compliance with this Section 13.3 shall be null and void.

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# 13.4 Notices.

(a) Each notice required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by a nationally recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, as follows:

If to MedImmune:

MedImmune, LLC One MedImmune Way Gaithersburg, MD 20878, USA Attention: Edward Bradley, Senior Vice President - Oncology

With a copy to:

MedImmune LLC One MedImmune Way Gaithersburg, MD 20878, USA Attention: General Counsel

# If to ADVAXIS:

Advaxis, Inc. 305 College Road East Princeton, New Jersey 08540 Attention: Chief Executive Officer

With a copy to (but not for Notice purposes):

Pearl Cohen Zedek Latzer Baratz, LLP 1500 Broadway, 12<sup>th</sup> Floor New York, New York 10036 Attention: Mark Cohen

(b) Such notice shall be deemed to have been received by the other Party (i) when delivered if personally delivered on a business day; (ii) on the business day after dispatch if sent by nationally-recognized overnight courier; or (iii) on the fifth (5th) business day following the date of mailing if sent by mail. A Party may change its address by giving written notice delivered in accordance with this Section.

**13.5 Applicable Law and Jurisdiction.** This Agreement shall be governed by, subject to, and construed in accordance with the substantive laws of Delaware, without regard for any choice or conflict of laws rule or provision that would result in the application of the substantive law of any other jurisdiction.

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- **13.6 Waivers.** The waiver by a Party of a breach or default under any provision under this Agreement or the failure of such party to exercise its rights under this Agreement in any instance shall not operate or be construed as a continuing waiver or a waiver of any subsequent breach or default. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provision hereof (whether or not similar).
- **13.7 Entire Agreement.** The terms and provisions contained in this Agreement (including the Appendixes) constitute the entire understanding of the Parties with respect to the transactions and matters contemplated hereby and supersede all previous communications, representations, agreements and understandings relating to the subject matter hereof. No agreement or understanding extending this Agreement or varying its terms shall be binding upon either party unless it is in a writing specifically referring to this Agreement and signed by a duly authorized representative of the applicable Party.
- **13.8 Severability.** In the event that any one or more of the provisions contained in this Agreement shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provision of this Agreement and such invalid or unenforceable provision shall be construed by limiting it so as to be valid and enforceable to the maximum extent compatible with, and possible under, Applicable Laws.
- **13.9 Binding Effect; Benefits.** This Agreement shall inure to the benefit of and be binding upon the Parties and their respective successors and permitted assigns; nothing in this Agreement, expressed or implied, is intended to confer on any person or entity other than the Parties hereto or, as applicable, their respective successors and permitted assigns, any rights, remedies, obligations or liabilities under or by reason of this Agreement.

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- **13.10 Headings.** The section numbers and headings are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.
- **13.11 Further Assurances.** Each Party covenants and agrees that, subsequent to the execution and delivery of this Agreement and without any additional consideration, it will execute and deliver any further legal instruments and perform any acts which are or may become reasonably necessary to effectuate the purposes of this Agreement.
- **13.12 Rules of Construction.** The Parties agree that they have participated equally in the formation of this Agreement and that the language and terms of this Agreement shall not be construed against a Party by reason of the extent to which such Party or its professional advisors participated in the preparation of this Agreement.
- **13.13 Counterparts.** This Agreement may be executed in multiple counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Facsimile or Portable Document Format signatures shall be accepted as original signatures and may be transmitted electronically and any document created pursuant to this Agreement may be maintained in an electronic document storage and retrieval system, a copy of which shall be considered an original.

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IN WITNESS WHEREOF the Parties have caused this Agreement to be executed on their behalf by their duly authorized representatives as of the Effective Date.

MEDIMMUNE, LLC ADVAXIS, INC.

By: /s/ Edward Bradley By: /s/ Daniel J. O'Connor

Name: Edward Bradley Name: Daniel J. O'Connor

Title: SVP, R&D Oncology iMED Head Title: President and Chief Executive Officer

Date: July 21, 2014 Date: July 21, 2014

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# <u>Appendix A</u>

# **Protocol Concept Sheet**

# Synopsis

| <b>Sponsor:</b><br>Advaxis, Inc.  | Name of Finished Product:<br>ADXS11-001<br>MEDI-4736  | <b>Type of Treatment: ADXS11-001</b> is a live, attenuated <i>Listeria monocytogenes (Lm)</i> based vector bioengineered to secrete a fusion peptide of tLLO-HPV (human papillomavirus) E7. |  |  |
|---|---|---|--|--|
|   |   | MEDI-4736 Programmed death-ligand 1 (PD-L1) also known as cluster of differentiation 274 (CD274) or B7 homolog 1 (B7-H1).   |  |  |
| Study Title:  |   |   |  |  |
| Phase 1-2 Study of<br>& Neck Cancer   | ADXS11-001 or MEDI-4376 Alone or Combina  | ation In Previously Treated Locally Advanced or Metastatic HPV+ Cervical or Head  |  |  |
| Type of Study:  |   |   |  |  |
|   | label Phase 1 with Phase 2 expansion cohort   |   |  |  |
| Study Centers:  |   |   |  |  |
| Multicenter: 1. Geo   | orgia Reagents University Cancer Center, [c.i.] 2.  | Others to be determined.  |  |  |
| Objectives:   |   |   |  |  |
| Primary objective:  | Phase 1   |   |  |  |
|   | safety and tolerability of ADXS11-001 or ME previously treated locally advanced or metastatic | EDI-4736 alone and in combination (ADXS11-001 + MEDI-4736) administered in EHPV+ head & neck cancer   |  |  |
|   |   | ty, evidence of clinical activity and correlative studies   |  |  |
| Primary Objective:  | Phase 2 expansion   |   |  |  |
| • To develop an estimate of clinical activity including: tumor responses, progression-free survival (PFS) by immune-related response evaluation criteria (irRECIST) and overall survival for a Phase 2 efficacy estimate. |   |   |  |  |
| Secondary Objectiv  | ves   |   |  |  |
| • Describe and eva  | luate data from correlative immunologic and path  | hologic studies, along with other exploratory investigations to patient outcomes.   |  |  |
| Methodology: [c.i.  | ]   |   |  |  |
| The Number of Pa  | tients Planned:   |   |  |  |
| [c.i]   |   |   |  |  |
| Diagnosis and Main Criteria for Eligibility:  [c.i.]  |   |   |  |  |
| Test Product, Dose, Mode of Administration:   |   |   |  |  |
| [c.i.]  |   |   |  |  |
| Reference Therapy:  |   |   |  |  |
| [c.i.]  |   |   |  |  |
| Study Duration:   |   |   |  |  |
| [c.i.] Criteria for Evaluation:   |   |   |  |  |
| [c.i.]  |   |   |  |  |
| Statistical Methods:  |   |   |  |  |
| [c.i.]  |   |   |  |  |

| <u>Schema</u> |  |                             |
|---------------|--|-----------------------------|
| [c.i.]        |  |                             |
| Table 1       | Schedule of Dosing and Efficacy Assessments-ADXS11-001 Monotherapy                     |                             |
| [c.i.]        |  |                             |
| Table 2       | Schedule of Dosing and Efficacy Assessments–MEDI-4736 Monotherapy                      |                             |
| [c.i.]        |  |                             |
| Table 3       | Schedule of Dosing and Efficacy Assessments-ADXS11-001 + MEDI-4736 Combination Therapy |                             |
| [c.i.]        |  |                             |
|               |  | Page <b>56</b> of <b>57</b> |

# Appendix B

# Samples Analysis/Assays Procedures

[<u>c.i.]</u>

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## UNIVERSITY OF PENNSYLVANIA

## Fifth Amendment to Amended and Restated License Agreement

This Fifth Amendment (the "Fifth Amendment") is made and entered into as of July 25, 2014 (the "Effective Date") by and between The Trustees of the University of Pennsylvania ("Penn") and Advaxis, Inc., a corporation organized and existing under the laws of Delaware ("Company") having a place of business at 305 College Road East, Princeton, New Jersey 08540, amends the Amended and Restated License Agreement dated February 13, 2007, as amended by the First Amendment to the License Agreement dated May 10,2010, the Third Amendment to the License Agreement dated December 12, 2011 and the Fourth Amendment to the License Agreement dated May 14, 2013 (the "License Agreement").

#### **BACKGROUND**

The License Agreement relates to certain intellectual property developed by Dr, Yvonne Paterson of Perm's School of Medicine, which intellectual property is the subject of patents or patent applications (the "Penn Dockets". The parties intend to eliminate or delay certain payments that are anticipated to come due in the near term absent this amendment and, to add or modify a series of payments in anticipation of success of Company, to be calculated on cumulative sales of Company products that may occur either during or after the expiration of the Penn Patent Rights. The parties wish to amend the License Agreement to reflect these changes.

Now, therefore, the parties hereby agree as follows:

- 1) New section 1.6 is hereby added after section 1.5 as follows:
- 1.6 "GLOBAL SALES" means combined gross sales in all countries in all fields for all human and non-human uses of (a) Penn Licensed Products and (b) any product that would have been a Penn Licensed Product at the time of approval in any country for any use, assuming that there were Valid Claims under the Penn Patent Rights in all countries of the world and that Valid Claims never expired, less qualifying costs. Such qualifying costs shall be limited to the following:
  - 1.6.1 Discounts, in amounts customary in the trade, for quantity purchases prompt payments and for wholesalers and distributors.
  - 1.6.2 Credits or refunds, not exceeding the original invoice amount, for claims or returns.

- 1.6.3 Prepaid outbound transportation expenses and transportation insurance premiums,
- 1.6.4 Sales and use taxes and other fees, duties, and imports imposed by any governmental agency."
- 2) Section 3.1.3 of the License Agreement is hereby amended and restated in its entirety as follows:
- 3.1.3 In further considerate on of the exclusive license granted to COMPANY, COMPANY must pay to PENN, on a quarterly basis, royalties on the annual, worldwide NET SALES of PENN LICENSED PRODUCTS as follows:
- (a) 2.5% of NET SALES in the TERRITORY for annual NET SALES from \$0 to \$250,000,000 and (b) 2.75% of annual NET SALES in excess of \$250,000,000.

For clarity, annual NET SALES means total NET SALES in each calendar year."

- 3) Sections 3.2.1 of the License Agreement is hereby amended and restated in its entirety as follows:
- 3.2.1. In partial consideration of the exclusive license granted to COMPANY, COMPANY will pay PENN the applicable milestone payment listed in the table below within thirty (30) days after achievement of each milestone event:

| Milestone   | <br>Payment     |
|---|-----------------|
| Regulatory approval of first PENN LICENSED PRODUCT for use in humans in the United States |                 |
| or any European country.  | \$<br>600,000   |
|   |                 |
| First Sale of PENN LICENSED PRODUCT in Primary Strategic Field for use in humans in the   |                 |
| United States or any European country, payable in installments as follows*:               | \$<br>2,500,000 |
|   |                 |
| payable within 45 days after initial Sale   | \$<br>1,000,000 |
|   |                 |
| Payable on or before First Anniversary of initial Sale                                    | \$<br>1,000,000 |
|   |                 |
| Payable on or before Second Anniversary of initial Sale                                   | \$<br>500,000   |
|   |                 |
| First Sale of PENN LICENSED PRODUCT in Secondary Strategic Field for use in humans in the |                 |
| United States or any European country.  | \$<br>1,000,000 |
|   |                 |
| TOTAL MILESTONE PAYMENTS:   | \$<br>4,100,000 |

<sup>\*</sup>For clarity, the total milestone triggered by first Sale of a Perm Licensed Product for use in humans in the US or any European country is \$2.5 Million, but payment is being delayed over 2 years, without interest. The obligation to make such delayed payment will survive termination or expiration of this Agreement for any reason."

- 4) Section 3.2.2 is hereby amended and restated as follows:
  - 3.2.2 Company shall pay to Penn the following sales milestone payments upon achievement of the following sales milestones:

## **Sales Milestones**

| Cumulative Global Sales of \$250 Million | \$<br>5,000,000  |
|--|------------------|
| Cumulative Global Sales of \$500 Million | \$<br>15,000,000 |
| Cumulative Global Sales of \$2 Billion   | \$<br>20,000,000 |
| TOTAL SALES MILESTONE PAYMENTS:          | \$<br>40,000,000 |

- 5) Section 3.2.3 is hereby intentionally deleted.
- 6) Section 5.7 is hereby amended and restated in its entirety as follows:
- 5.7 Company's obligations to pay all monies owed but not yet paid under this Agreement shall survive termination of this Agreement. In addition, the provisions of Sections 3.2.2, 3,4.2, 3.4.3, 3.4.4 and 3.5, Articles 4- Confidentiality, Article 5- Term and Termination, Article 8-Disclaimer of Warranties; Indemnification, Article 9- Use of Perm's Name; and Article 10- Additional Provisions shall survive such termination in accordance with their respective terms.
- 7) This Fifth Amendment, together with the License Agreement, constitute the entire agreement between the parties. All other terms and provisions of the License Agreement, except as expressly amended by this Fifth Amendment, remain in full, force and effect.
- 8) This Fifth Amendment may be executed in two or more counterparts, each of which shall be deemed an original and together shall be deemed one and the same instrument.

IN WITNESS WHEREOF, the parties, intending to be legally bound, have caused this Fifth Amendment to be executed by their duly authorized representatives.

# THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA

By: /s/ John Swartley

Name: John Swartley

Title: Associate Vice Provost for Research and Executive Director, PCI

Date: June 16, 2014

ADVAXIS, INC.

By: /s/ Daniel O'Connor

Name: Daniel O'Connor

Title: President and Chief Executive Officer

Date: June 20, 2014

# ADVAXIS, INC. AMENDED AND RESTATED 2011 OMNIBUS INCENTIVE PLAN

#### September 8, 2014

- 1. *Purpose.* The purpose of this AMENDED AND RESTATED 2011 OMNIBUS INCENTIVE PLAN (the "Plan") is to assist **ADVAXIS, INC.** (the "Company") and its Related Entities (as hereinafter defined) in attracting, motivating, retaining and rewarding high-quality executives and other employees, officers, directors, consultants and other persons who provide services to the Company or its Related Entities by enabling such persons to acquire or increase a proprietary interest in the Company in order to strengthen the mutuality of interests between such persons and the Company's shareholders, and providing such persons with annual and long term performance incentives to expend their maximum efforts in the creation of shareholder value.
- 2. *Definitions*. For purposes of the Plan, the following terms shall be defined as set forth below, in addition to such terms defined in Section 1 hereof and elsewhere herein.
- (a) "Award" means any Option, Stock Appreciation Right, Restricted Stock Award, Restricted Stock Unit Award, Share granted as a bonus or in lieu of another Award, Dividend Equivalent, Other Stock-Based Award or Performance Award, together with any other right or interest, granted to a Participant under the Plan.
- (b) "Award Agreement" means any written agreement, contract or other instrument or document evidencing any Award granted by the Committee hereunder.
- (c) "Beneficiary" means the person, persons, trust or trusts that have been designated by a Participant in his or her most recent written beneficiary designation filed with the Committee to receive the benefits specified under the Plan upon such Participant's death or to which Awards or other rights are transferred if and to the extent permitted under Section 10(b) hereof. If, upon a Participant's death, there is no designated Beneficiary or surviving designated Beneficiary, then the term Beneficiary means the person, persons, trust or trusts entitled by will or the laws of descent and distribution to receive such benefits.
- (d) "Beneficial Owner" and "Beneficial Ownership" shall have the meaning ascribed to such term in Rule 13d-3 under the Exchange Act and any successor to such Rule.
  - (e) "Board" means the Company's Board of Directors.
  - (f) "Change in Control" means a Change in Control as defined in Section 9(b) of the Plan.
- (g) "Code" means the Internal Revenue Code of 1986, as amended from time to time, including regulations thereunder and successor provisions and regulations thereto.
- (h) "Committee" means a committee designated by the Board to administer the Plan; provided, however, that if the Board fails to designate a committee or if there are no longer any members on the committee so designated by the Board, or for any other reason determined by the Board, then the Board shall serve as the Committee. While it is intended that the Committee shall consist of at least two directors, each of whom shall be (i) a "non-employee director" within the meaning of Rule 16b-3 (or any successor rule) under the Exchange Act, unless administration of the Plan by "non-employee directors" is not then required in order for exemptions under Rule 16b-3 to apply to transactions under the Plan, (ii) an "outside director" within the meaning of Section 162(m) of the Code, and (iii) "Independent", the failure of the Committee to be so comprised shall not invalidate any Award that otherwise satisfies the terms of the
- (i) "Consultant" means any Person (other than an Employee or a Director, solely with respect to rendering services in such Person's capacity as a director) who is engaged by the Company or any Related Entity to render consulting or advisory services to the Company or such Related Entity on a full-time basis.

- (j) "Continuous Service" means the uninterrupted provision of services to the Company or any Related Entity in any capacity of Employee, Director, Consultant or other service provider. Continuous Service shall not be considered to be interrupted in the case of (i) any approved leave of absence, (ii) transfers among the Company, any Related Entities, or any successor entities, in any capacity of Employee, Director, Consultant or other service provider, or (iii) any change in status as long as the individual remains in the service of the Company or a Related Entity in any capacity of Employee, Director, Consultant or other service provider (except as otherwise provided in the Award Agreement). An approved leave of absence shall include sick leave, military leave, or any other authorized personal leave.
- (k) "Covered Employee" means the Person who, as of the end of the taxable year, either is the principal executive officer of the Company or is serving as the acting principal executive officer of the Company, and each other Person whose compensation is required to be disclosed in the Company's filings with the Securities and Exchange Commission by reason of that person being among the three highest compensated officers of the Company as of the end of a taxable year, or such other person as shall be considered a "covered employee" for purposes of Section 162(m) of the Code.
  - (l) "Director" means a member of the Board.
- (m) "Disability" means a permanent and total disability (within the meaning of Section 22(e) of the Code), as determined by a medical doctor satisfactory to the Committee.
- (n) "Dividend Equivalent" means a right, granted to a Participant under Section 6(g) hereof, to receive cash, Shares, other Awards or other property equal in value to dividends paid with respect to a specified number of Shares, or other periodic payments.
  - (o) "Effective Date" means the effective date of the Plan, which shall be August 22, 2011.
- (p) "*Eligible Person*" means each officer, Director, Employee, Consultant and other person who provides services to the Company or any Related Entity. The foregoing notwithstanding, only Employees of the Company, or any parent corporation or subsidiary corporation of the Company (as those terms are defined in Sections 424(e) and (f) of the Code, respectively), shall be Eligible Persons for purposes of receiving any Incentive Stock Options. An Employee on leave of absence may, in the discretion of the Committee, be considered as still in the employ of the Company or a Related Entity for purposes of eligibility for participation in the Plan.
- (q) "*Employee*" means any person, including an officer or Director, who is a full-time employee of the Company or any Related Entity. The payment of a director's fee by the Company or a Related Entity shall not be sufficient to constitute "employment" by the Company.
- (r) "Exchange Act" means the Securities Exchange Act of 1934, as amended from time to time, including rules thereunder and successor provisions and rules thereto.
- (s) "Fair Market Value" means the fair market value of Shares, Awards or other property as determined by the Committee, or under procedures established by the Committee. Unless otherwise determined by the Committee, the Fair Market Value of a Share as of any given date shall be the closing sale price per Share reported on a consolidated basis for stock listed on the principal stock exchange or market on which Shares are traded on the date as of which such value is being determined (or as of such later measurement date as determined by the Committee on the date the Award is authorized by the Committee), or, if there is no sale on that date, then on the last previous day on which a sale was reported.
- (t) "Incentive Stock Option" means any Option intended to be designated as an incentive stock option within the meaning of Section 422 of the Code or any successor provision thereto.
- (u) "Independent", when referring to either the Board or members of the Committee, shall have the same meaning as used in the rules of the Listing Market.
  - (v) "Incumbent Board" means the Incumbent Board as defined in Section 9(b)(ii) hereof.
- (w) "Listing Market" means any national securities exchange on which any securities of the Company are listed for trading, and if not listed for trading, by the rules of the Nasdaq Market.
- (x) "*Option*" means a right granted to a Participant under Section 6(b) hereof, to purchase Shares or other Awards at a specified price during specified time periods.
  - (y) "Optionee" means a person to whom an Option is granted under this Plan or any person who succeeds to the rights of such person under this Plan.

- (z) "Other Stock-Based Awards" means Awards granted to a Participant under Section 6(i) hereof.
- (aa) "Participant" means a person who has been granted an Award under the Plan which remains outstanding, including a person who is no longer an Eligible Person.
  - (bb) "Performance Award" means any Award of Performance Shares or Performance Units granted pursuant to Section 6(h) hereof.
- (cc) "*Performance Period*" means that period established by the Committee at the time any Performance Award is granted or at any time thereafter during which any performance goals specified by the Committee with respect to such Award are to be measured.
- (dd) "Performance Share" means any grant pursuant to Section 6(h) hereof of a unit valued by reference to a designated number of Shares, which value may be paid to the Participant by delivery of such property as the Committee shall determine, including cash, Shares, other property, or any combination thereof, upon achievement of such performance goals during the Performance Period as the Committee shall establish at the time of such grant or thereafter.
- (ee) "Performance Unit" means any grant pursuant to Section 6(h) hereof of a unit valued by reference to a designated amount of property (including cash) other than Shares, which value may be paid to the Participant by delivery of such property as the Committee shall determine, including cash, Shares, other property, or any combination thereof, upon achievement of such performance goals during the Performance Period as the Committee shall establish at the time of such grant or thereafter.
- (ff) "*Person*" shall have the meaning ascribed to such term in Section 3(a)(9) of the Exchange Act and used in Sections 13(d) and 14(d) thereof, and shall include a "group" as defined in Section 13(d) thereof.
- (gg) "Prior Plans" means the Advaxis, Inc. 2004 Stock Option Plan, the Advaxis, Inc. 2005 Stock Option Plan and the Advaxis, Inc. Amended and Restated 2009 Stock Option Plan.
- (hh) "*Related Entity*" means any Subsidiary, and any business, corporation, partnership, limited liability company or other entity designated by the Board, in which the Company or a Subsidiary holds a substantial ownership interest, directly or indirectly.
- (ii) "Restriction Period" means the period of time specified by the Committee that Restricted Stock Awards shall be subject to such restrictions on transferability, risk of forfeiture and other restrictions, if any, as the Committee may impose.
- (jj) "Restricted Stock" means any Share issued with the restriction that the holder may not sell, transfer, pledge or assign such Share and with such risks of forfeiture and other restrictions as the Committee, in its sole discretion, may impose (including any restriction on the right to vote such Share and the right to receive any dividends), which restrictions may lapse separately or in combination at such time or times, in installments or otherwise, as the Committee may deem appropriate.
  - (kk) "Restricted Stock Award" means an Award granted to a Participant under Section 6(d) hereof.
- (ll) "Restricted Stock Units" means a right to receive Shares, including Restricted Stock, cash measured based upon the value of Shares or a combination thereof, at the end of a specified deferral period.
  - (mm) "Restricted Stock Unit Award" means an Award of Restricted Stock Units granted to a Participant under Section 6(e) hereof.
- (nn) "Rule 16b-3" means Rule 16b-3, as from time to time in effect and applicable to the Plan and Participants, promulgated by the Securities and Exchange Commission under Section 16 of the Exchange Act.
- (oo) "Shareholder Approval Date" means the date on which this Plan is approved by the shareholders of the Company eligible to vote in the election of directors, by a vote sufficient to meet the requirements of Sections 162(m) (if applicable) and 422 of the Code, Rule 16b-3 under the Exchange Act (if applicable), applicable requirements under the rules of any stock exchange or automated quotation system on which the Shares may be listed on quoted, and other laws, regulations and obligations of the Company applicable to the Plan.

- (pp) "Shares" means the shares of common stock of the Company, par value \$0.001 per share, and such other securities as may be substituted (or resubstituted) for Shares pursuant to Section 10(c) hereof.
  - (qq) "Stock Appreciation Right" means a right granted to a Participant under Section 6(c) hereof.
- (rr) "*Subsidiary*" means any corporation or other entity in which the Company has a direct or indirect ownership interest of 50% or more of the total combined voting power of the then outstanding securities or interests of such corporation or other entity entitled to vote generally in the election of directors or in which the Company has the right to receive 50% or more of the distribution of profits or 50% or more of the assets on liquidation or dissolution.
- (ss) "Substitute Awards" means Awards granted or Shares issued by the Company in assumption of, or in substitution or exchange for, Awards previously granted, or the right or obligation to make future Awards, by a company (i) acquired by the Company or any Related Entity, (ii) which becomes a Related Entity after the date hereof, or (iii) with which the Company or any Related Entity combines.

#### 3. Administration.

- (a) *Authority of the Committee.* The Plan shall be administered by the Committee, except to the extent (and subject to the limitations imposed by Section 3(b) hereof) the Board elects to administer the Plan, in which case the Plan shall be administered by only those members of the Board who are Independent members of the Board, in which case references herein to the "Committee" shall be deemed to include references to the Independent members of the Board. The Committee shall have full and final authority, subject to and consistent with the provisions of the Plan, to select Eligible Persons to become Participants, grant Awards, determine the type, number and other terms and conditions of, and all other matters relating to, Awards, prescribe Award Agreements (which need not be identical for each Participant) and rules and regulations for the administration of the Plan, construe and interpret the Plan and Award Agreements and correct defects, supply omissions or reconcile inconsistencies therein, and to make all other decisions and determinations as the Committee may deem necessary or advisable for the administration of the Plan. In exercising any discretion granted to the Committee under the Plan or pursuant to any Award, the Committee shall not be required to follow past practices, act in a manner consistent with past practices, or treat any Eligible Person or Participant in a manner consistent with the treatment of any other Eligible Persons or Participants.
- (b) *Manner of Exercise of Committee Authority.* The Committee, and not the Board, shall exercise sole and exclusive discretion (i) on any matter relating to a Participant then subject to Section 16 of the Exchange Act with respect to the Company to the extent necessary in order that transactions by such Participant shall be exempt under Rule 16b-3 under the Exchange Act, (ii) with respect to any Award that is intended to qualify as "performance-based compensation" under Section 162(m), to the extent necessary in order for such Award to so qualify; and (iii) with respect to any Award to an Independent Director. Any action of the Committee shall be final, conclusive and binding on all persons, including the Company, its Related Entities, Eligible Persons, Participants, Beneficiaries, transferees under Section 10(b) hereof or other persons claiming rights from or through a Participant, and shareholders. The express grant of any specific power to the Committee, and the taking of any action by the Committee, shall not be construed as limiting any power or authority of the Committee. The Committee may delegate to officers or managers of the Company or any Related Entity, or committees thereof, the authority, subject to such terms and limitations as the Committee shall determine, to perform such functions, including administrative functions as the Committee may determine to the extent that such delegation will not result in the loss of an exemption under Rule 16b-3(d)(1) for Awards granted to Participants subject to Section 16 of the Exchange Act in respect of the Company and will not cause Awards intended to qualify as "performance-based compensation" under Code Section 162(m) to fail to so qualify. The Committee may appoint agents to assist it in administering the Plan.

(c) *Limitation of Liability.* The Committee and the Board, and each member thereof, shall be entitled to, in good faith, rely or act upon any report or other information furnished to him or her by any officer or Employee, the Company's independent auditors, Consultants or any other agents assisting in the administration of the Plan. Members of the Committee and the Board, and any officer or Employee acting at the direction or on behalf of the Committee or the Board, shall not be personally liable for any action or determination taken or made in good faith with respect to the Plan, and shall, to the extent permitted by law, be fully indemnified and protected by the Company with respect to any such action or determination.

## 4. Shares Subject to Plan.

- (a) *Limitation on Overall Number of Shares Available for Delivery Under Plan.* Subject to adjustment as provided in Section 10(c) hereof, the total number of Shares reserved and available for delivery under the Plan shall be Two Million One Hundred Twenty Thousand 2,120,000. Any Shares that are subject to Awards shall be counted against this limit as one (1) Share for every one (1) Share granted. Any Shares delivered under the Plan may consist, in whole or in part, of authorized and unissued shares or treasury shares.
- (b) *Application of Limitation to Grants of Awards*. No Award may be granted if the number of Shares to be delivered in connection with such an Award exceeds the number of Shares remaining available for delivery under the Plan, minus the number of Shares deliverable in settlement of or relating to then outstanding Awards. The Committee may adopt reasonable counting procedures to ensure appropriate counting, avoid double counting (as, for example, in the case of tandem or substitute awards) and make adjustments if the number of Shares actually delivered differs from the number of Shares previously counted in connection with an Award.

## (c) Availability of Shares Not Delivered under Awards and Adjustments to Limits.

- (i) If any Awards are forfeited, expire or otherwise terminate without issuance of such Shares, or any Award is settled for cash or otherwise does not result in the issuance of all or a portion of the Shares subject to such Award, the Shares to which those Awards were subject, shall, to the extent of such forfeiture, expiration, termination, cash settlement or non-issuance, again be available for delivery with respect to Awards under the Plan.
- (ii) In the event that any Option or other Award granted hereunder is exercised through the tendering of Shares (either actually or by attestation) or by the withholding of Shares by the Company, or withholding tax liabilities arising from such option or other award are satisfied by the tendering of Shares (either actually or by attestation) or by the withholding of Shares by the Company, then only the number of Shares issued net of the Shares tendered or withheld shall be counted for purposes of determining the maximum number of Shares available for grant under the Plan.
- (iii) Substitute Awards shall not reduce the Shares authorized for delivery under the Plan or authorized for delivery to a Participant in any period. Additionally, in the event that a company acquired by the Company or any Related Entity or with which the Company or any Related Entity combines has shares available under a pre-existing plan approved by its shareholders, the shares available for delivery pursuant to the terms of such pre-existing plan (as adjusted, to the extent appropriate, using the exchange ratio or other adjustment or valuation ratio or formula used in such acquisition or combination to determine the consideration payable to the holders of common stock of the entities party to such acquisition or combination) may be used for Awards under the Plan and shall not reduce the Shares authorized for delivery under the Plan; if and to the extent that the use of such Shares would not require approval of the Company's shareholders under the rules of the Listing Market.
  - (iv) Any Share that again becomes available for delivery pursuant to this Section 4(c) shall be added back as one (1) Share.
- (v) Notwithstanding anything in this Section 4(c) to the contrary but subject to adjustment as provided in Section 10(c) hereof, the maximum aggregate number of Shares that may be delivered under the Plan as a result of the exercise of the Incentive Stock Options shall be Two Million One Hundred Twenty Thousand(2,120,000) Shares.
- (d) No Further Awards Under Prior Plans. In light of the adoption of this Plan, no further awards shall be made under the Prior Plans after the Shareholder Approval Date.

5. *Eligibility; Per-Person Award Limitations*. Awards may be granted under the Plan only to Eligible Persons. Subject to adjustment as provided in Section 10(c), in any fiscal year of the Company during any part of which the Plan is in effect, no Participant may be granted (i) Options or Stock Appreciation Rights with respect to more than Two Hundred Fifty Thousand (250,000) Shares or (ii) Restricted Stock, Restricted Stock Units, Performance Shares and/or Other Stock-Based Awards with respect to more than Two Hundred Fifty Thousand (2500,000) Shares. In addition, the maximum dollar value payable to any one Participant with respect to Performance Units is (x) Two Million Five Hundred Thousand Dollars (\$2,500,000) with respect to any 12 month Performance Period (pro-rated for any Performance Period that is less than 12 months based upon the ratio of the number of days in the Performance Period as compared to 365), and (y) with respect to any Performance Period that is more than 12 months, Two Million Dollars (\$2,000,000) multiplied by the number of full 12 month periods that are in the Performance Period.

## 6. Specific Terms of Awards.

- (a) *General.* Awards may be granted on the terms and conditions set forth in this Section 6. In addition, the Committee may impose on any Award or the exercise thereof, at the date of grant or thereafter (subject to Section 10(e)), such additional terms and conditions, not inconsistent with the provisions of the Plan, as the Committee shall determine, including terms requiring forfeiture of Awards in the event of termination of the Participant's Continuous Service and terms permitting a Participant to make elections relating to his or her Award. Except as otherwise expressly provided herein, the Committee shall retain full power and discretion to accelerate, waive or modify, at any time, any term or condition of an Award that is not mandatory under the Plan. Except in cases in which the Committee is authorized to require other forms of consideration under the Plan, or to the extent other forms of consideration must be paid to satisfy the requirements of New York law, no consideration other than services may be required for the grant (as opposed to the exercise) of any Award.
  - (b) Options. The Committee is authorized to grant Options to any Eligible Person on the following terms and conditions:
  - (i) *Exercise Price.* Other than in connection with Substitute Awards, the exercise price per Share purchasable under an Option shall be determined by the Committee, provided that such exercise price shall not be less than 100% of the Fair Market Value of a Share on the date of grant of the Option and shall not, in any event, be less than the par value of a Share on the date of grant of the Option. If an Employee owns or is deemed to own (by reason of the attribution rules applicable under Section 424(d) of the Code) more than 10% of the combined voting power of all classes of stock of the Company (or any parent corporation or subsidiary corporation of the Company, as those terms are defined in Sections 424(e) and (f) of the Code, respectively) and an Incentive Stock Option is granted to such Employee, the exercise price of such Incentive Stock Option (to the extent required by the Code at the time of grant) shall be no less than 110% of the Fair Market Value of a Share on the date such Incentive Stock Option is granted. Other than pursuant to Section 10(c)(i) and (ii), the Committee shall not be permitted to (A) lower the exercise price per Share of an Option after it is granted, (B) cancel an Option when the exercise price per Share exceeds the Fair Market Value of the underlying Shares in exchange for another Award (other than in connection with Substitute Awards), or (C) take any other action with respect to an Option that may be treated as a repricing pursuant to the applicable rules of the Listing Market, without approval of the Company's shareholders.
  - (ii) *Time and Method of Exercise*. The Committee shall determine the time or times at which or the circumstances under which an Option may be exercised in whole or in part (including based on achievement of performance goals and/or future service requirements), the time or times at which Options shall cease to be or become exercisable following termination of Continuous Service or upon other conditions, the methods by which the exercise price may be paid or deemed to be paid (including in the discretion of the Committee a cashless exercise procedure), the form of such payment, including, without limitation, cash, Shares (including without limitation the withholding of Shares otherwise deliverable pursuant to the Award), other Awards or awards granted under other plans of the Company or a Related Entity, or other property (including notes or other contractual obligations of Participants to make payment on a deferred basis provided that such deferred payments are not in violation of Section 13(k) of the Exchange Act, or any rule or regulation adopted thereunder or any other applicable law), and the methods by or forms in which Shares will be delivered or deemed to be delivered to Participants.

- (iii) *Incentive Stock Options*. The terms of any Incentive Stock Option granted under the Plan shall comply in all respects with the provisions of Section 422 of the Code. Anything in the Plan to the contrary notwithstanding, no term of the Plan relating to Incentive Stock Options (including any Stock Appreciation Right issued in tandem therewith) shall be interpreted, amended or altered, nor shall any discretion or authority granted under the Plan be exercised, so as to disqualify either the Plan or any Incentive Stock Option under Section 422 of the Code, unless the Participant has first requested, or consents to, the change that will result in such disqualification. Thus, if and to the extent required to comply with Section 422 of the Code, Options granted as Incentive Stock Options shall be subject to the following special terms and conditions:
  - (A) the Option shall not be exercisable for more than ten years after the date such Incentive Stock Option is granted; provided, however, that if a Participant owns or is deemed to own (by reason of the attribution rules of Section 424(d) of the Code) more than 10% of the combined voting power of all classes of stock of the Company (or any parent corporation or subsidiary corporation of the Company, as those terms are defined in Sections 424(e) and (f) of the Code, respectively) and the Incentive Stock Option is granted to such Participant, the term of the Incentive Stock Option shall be (to the extent required by the Code at the time of the grant) for no more than five years from the date of grant; and
  - (B) The aggregate Fair Market Value (determined as of the date the Incentive Stock Option is granted) of the Shares with respect to which Incentive Stock Options granted under the Plan and all other option plans of the Company (and any parent corporation or subsidiary corporation of the Company, as those terms are defined in Sections 424(e) and (f) of the Code, respectively) that become exercisable for the first time by the Participant during any calendar year shall not (to the extent required by the Code at the time of the grant) exceed \$100,000.
- (c) *Stock Appreciation Rights.* The Committee may grant Stock Appreciation Rights to any Eligible Person in conjunction with all or part of any Option granted under the Plan or at any subsequent time during the term of such Option (a "Tandem Stock Appreciation Right"), or without regard to any Option (a "Freestanding Stock Appreciation Right"), in each case upon such terms and conditions as the Committee may establish in its sole discretion, not inconsistent with the provisions of the Plan, including the following:
  - (i) *Right to Payment.* A Stock Appreciation Right shall confer on the Participant to whom it is granted a right to receive, upon exercise thereof, the excess of (A) the Fair Market Value of one Share on the date of exercise over (B) the grant price of the Stock Appreciation Right as determined by the Committee. The grant price of a Stock Appreciation Right shall not be less than 100% of the Fair Market Value of a Share on the date of grant, in the case of a Freestanding Stock Appreciation Right, or less than the associated Option exercise price, in the case of a Tandem Stock Appreciation Right. Other than pursuant to Section 10(c)(i) and (ii), the Committee shall not be permitted to (A) lower the grant price per Share of a Stock Appreciation Right after it is granted, (B) cancel a Stock Appreciation Right when the grant price per Share exceeds the Fair Market Value of the underlying Shares in exchange for another Award (other than in connection with Substitute Awards), or (C) take any other action with respect to a Stock Appreciation Right that may be treated as a repricing pursuant to the applicable rules of the Listing Market, without shareholder approval.

- (ii) *Other Terms.* The Committee shall determine at the date of grant or thereafter, the time or times at which and the circumstances under which a Stock Appreciation Right may be exercised in whole or in part (including based on achievement of performance goals and/or future service requirements), the time or times at which Stock Appreciation Rights shall cease to be or become exercisable following termination of Continuous Service or upon other conditions, the method of exercise, method of settlement, form of consideration payable in settlement, method by or forms in which Shares will be delivered or deemed to be delivered to Participants, whether or not a Stock Appreciation Right shall be in tandem or in combination with any other Award, and any other terms and conditions of any Stock Appreciation Right.
- (iii) *Tandem Stock Appreciation Rights.* Any Tandem Stock Appreciation Right may be granted at the same time as the related Option is granted or, for Options that are not Incentive Stock Options, at any time thereafter before exercise or expiration of such Option. Any Tandem Stock Appreciation Right related to an Option may be exercised only when the related Option would be exercisable and the Fair Market Value of the Shares subject to the related Option exceeds the exercise price at which Shares can be acquired pursuant to the Option. In addition, if a Tandem Stock Appreciation Right exists with respect to less than the full number of Shares covered by a related Option, then an exercise or termination of such Option shall not reduce the number of Shares to which the Tandem Stock Appreciation Right applies until the number of Shares then exercisable under such Option equals the number of Shares to which the Tandem Stock Appreciation Right applies. Any Option related to a Tandem Stock Appreciation Right shall no longer be exercisable to the extent the Tandem Stock Appreciation Right has been exercised, and any Tandem Stock Appreciation Right shall no longer be exercisable to the extent the related Option has been exercised.
- (d) *Restricted Stock Awards*. The Committee is authorized to grant Restricted Stock Awards to any Eligible Person on the following terms and conditions:
  - (i) *Grant and Restrictions*. Restricted Stock Awards shall be subject to such restrictions on transferability, risk of forfeiture and other restrictions, if any, as the Committee may impose, or as otherwise provided in this Plan during the Restriction Period. The terms of any Restricted Stock Award granted under the Plan shall be set forth in a written Award Agreement which shall contain provisions determined by the Committee and not inconsistent with the Plan. The restrictions may lapse separately or in combination at such times, under such circumstances (including based on achievement of performance goals and/or future service requirements), in such installments or otherwise, as the Committee may determine at the date of grant or thereafter. Except to the extent restricted under the terms of the Plan and any Award Agreement relating to a Restricted Stock Award, a Participant granted Restricted Stock shall have all of the rights of a shareholder, including the right to vote the Restricted Stock and the right to receive dividends thereon (subject to any mandatory reinvestment or other requirement imposed by the Committee). During the period that the Restriction Stock Award is subject to a risk of forfeiture, subject to Section 10(b) below and except as otherwise provided in the Award Agreement, the Restricted Stock may not be sold, transferred, pledged, hypothecated, margined or otherwise encumbered by the Participant.
  - (ii) *Forfeiture*. Except as otherwise determined by the Committee, upon termination of a Participant's Continuous Service during the applicable Restriction Period, the Participant's Restricted Stock that is at that time subject to a risk of forfeiture that has not lapsed or otherwise been satisfied shall be forfeited and reacquired by the Company; provided that the Committee may provide, by rule or regulation or in any Award Agreement, or may determine in any individual case, that forfeiture conditions relating to Restricted Stock Awards shall be waived in whole or in part in the event of terminations resulting from specified causes, and the Committee may in other cases waive in whole or in part the forfeiture of Restricted Stock.
  - (iii) *Certificates for Stock.* Restricted Stock granted under the Plan may be evidenced in such manner as the Committee shall determine. If certificates representing Restricted Stock are registered in the name of the Participant, the Committee may require that such certificates bear an appropriate legend referring to the terms, conditions and restrictions applicable to such Restricted Stock, that the Company retain physical possession of the certificates, and that the Participant deliver a stock power to the Company, endorsed in blank, relating to the Restricted Stock.

- (iv) *Dividends and Splits.* As a condition to the grant of a Restricted Stock Award, the Committee may require or permit a Participant to elect that any cash dividends paid on a Share of Restricted Stock be automatically reinvested in additional Shares of Restricted Stock or applied to the purchase of additional Awards under the Plan. Unless otherwise determined by the Committee, Shares distributed in connection with a stock split or stock dividend, and other property distributed as a dividend, shall be subject to restrictions and a risk of forfeiture to the same extent as the Restricted Stock with respect to which such Shares or other property have been distributed.
- (e) *Restricted Stock Unit Award*. The Committee is authorized to grant Restricted Stock Unit Awards to any Eligible Person on the following terms and conditions:
  - (i) Award and Restrictions. Satisfaction of a Restricted Stock Unit Award shall occur upon expiration of the deferral period specified for such Restricted Stock Unit Award by the Committee (or, if permitted by the Committee, as elected by the Participant). In addition, a Restricted Stock Unit Award shall be subject to such restrictions (which may include a risk of forfeiture) as the Committee may impose, if any, which restrictions may lapse at the expiration of the deferral period or at earlier specified times (including based on achievement of performance goals and/or future service requirements), separately or in combination, in installments or otherwise, as the Committee may determine. A Restricted Stock Unit Award may be satisfied by delivery of Shares, cash equal to the Fair Market Value of the specified number of Shares covered by the Restricted Stock Units, or a combination thereof, as determined by the Committee at the date of grant or thereafter. Prior to satisfaction of a Restricted Stock Unit Award, a Restricted Stock Unit Award carries no voting or dividend or other rights associated with Share ownership.
  - (ii) *Forfeiture*. Except as otherwise determined by the Committee, upon termination of a Participant's Continuous Service during the applicable deferral period or portion thereof to which forfeiture conditions apply (as provided in the Award Agreement evidencing the Restricted Stock Unit Award), the Participant's Restricted Stock Unit Award that is at that time subject to a risk of forfeiture that has not lapsed or otherwise been satisfied shall be forfeited; provided that the Committee may provide, by rule or regulation or in any Award Agreement, or may determine in any individual case, that forfeiture conditions relating to a Restricted Stock Unit Award shall be waived in whole or in part in the event of terminations resulting from specified causes, and the Committee may in other cases waive in whole or in part the forfeiture of any Restricted Stock Unit Award.
  - (iii) *Dividend Equivalents*. Unless otherwise determined by the Committee at the date of grant, any Dividend Equivalents that are granted with respect to any Restricted Stock Unit Award shall be either (A) paid with respect to such Restricted Stock Unit Award at the dividend payment date in cash or in Shares of unrestricted stock having a Fair Market Value equal to the amount of such dividends, or (B) deferred with respect to such Restricted Stock Unit Award and the amount or value thereof automatically deemed reinvested in additional Restricted Stock Units, other Awards or other investment vehicles, as the Committee shall determine or permit the Participant to elect. The applicable Award Agreement shall specify whether any Dividend Equivalents shall be paid at the dividend payment date, deferred or deferred at the election of the Participant. If the Participant may elect to defer the Dividend Equivalents, such election shall be made within 30 days after the grant date of the Restricted Stock Unit Award, but in no event later than 12 months before the first date on which any portion of such Restricted Stock Unit Award vests (or at such other times prescribed by the Committee as shall not result in a violation of Section 409A of the Code).
- (f) *Bonus Stock and Awards in Lieu of Obligations*. The Committee is authorized to grant Shares to any Eligible Persons as a bonus, or to grant Shares or other Awards in lieu of obligations to pay cash or deliver other property under the Plan or under other plans or compensatory arrangements, provided that, in the case of Eligible Persons subject to Section 16 of the Exchange Act, the amount of such grants remains within the discretion of the Committee to the extent necessary to ensure that acquisitions of Shares or other Awards are exempt from liability under Section 16(b) of the Exchange Act. Shares or Awards granted hereunder shall be subject to such other terms as shall be determined by the Committee.

- (g) *Dividend Equivalents*. The Committee is authorized to grant Dividend Equivalents to any Eligible Person entitling the Eligible Person to receive cash, Shares, other Awards, or other property equal in value to the regular dividends paid with respect to a specified number of Shares, or other periodic payments. Dividend Equivalents may be awarded on a free-standing basis or in connection with another Award. The Committee may provide that Dividend Equivalents shall be paid or distributed when accrued or shall be deemed to have been reinvested in additional Shares, Awards, or other investment vehicles, and subject to such restrictions on transferability and risks of forfeiture, as the Committee may specify. Any such determination by the Committee shall be made at the grant date of the applicable Award.
- (h) *Performance Awards*. The Committee is authorized to grant Performance Awards to any Eligible Person payable in cash, Shares, or other Awards, on terms and conditions established by the Committee, subject to the provisions of Section 8 if and to the extent that the Committee shall, in its sole discretion, determine that an Award shall be subject to those provisions. The performance criteria to be achieved during any Performance Period and the length of the Performance Period shall be determined by the Committee upon the grant of each Performance Award. Except as provided in Section 9 or as may be provided in an Award Agreement, Performance Awards will be distributed only after the end of the relevant Performance Period. The performance goals to be achieved for each Performance Period shall be conclusively determined by the Committee and may be based upon the criteria set forth in Section 8(b), or in the case of an Award that the Committee determines shall not be subject to Section 8 hereof, any other criteria that the Committee, in its sole discretion, shall determine should be used for that purpose. The amount of the Award to be distributed shall be conclusively determined by the Committee. Performance Awards may be paid in a lump sum or in installments following the close of the Performance Period or, in accordance with procedures established by the Committee, on a deferred basis in a manner that does not violate the requirements of Section 409A of the Code.
- (i) *Other Stock-Based Awards*. The Committee is authorized, subject to limitations under applicable law, to grant to any Eligible Person such other Awards that may be denominated or payable in, valued in whole or in part by reference to, or otherwise based on, or related to, Shares, as deemed by the Committee to be consistent with the purposes of the Plan. Other Stock-Based Awards may be granted to Participants either alone or in addition to other Awards granted under the Plan, and such Other Stock-Based Awards shall also be available as a form of payment in the settlement of other Awards granted under the Plan. The Committee shall determine the terms and conditions of such Awards. Shares delivered pursuant to an Award in the nature of a purchase right granted under this Section 6(i) shall be purchased for such consideration, (including without limitation loans from the Company or a Related Entity provided that such loans are not in violation of Section 13(k) of the Exchange Act, or any rule or regulation adopted thereunder or any other applicable law) paid for at such times, by such methods, and in such forms, including, without limitation, cash, Shares, other Awards or other property, as the Committee shall determine.

### 7. Certain Provisions Applicable to Awards.

(a) *Stand-Alone, Additional, Tandem, and Substitute Awards.* Awards granted under the Plan may, in the discretion of the Committee, be granted either alone or in addition to, in tandem with, or in substitution or exchange for, any other Award or any award granted under another plan of the Company, any Related Entity, or any business entity to be acquired by the Company or a Related Entity, or any other right of a Participant to receive payment from the Company or any Related Entity. Such additional, tandem, and substitute or exchange Awards may be granted at any time. If an Award is granted in substitution or exchange for another Award or award, the Committee shall require the surrender of such other Award or award in consideration for the grant of the new Award. In addition, Awards may be granted in lieu of cash compensation, including in lieu of cash amounts payable under other plans of the Company or any Related Entity, in which the value of Shares subject to the Award is equivalent in value to the cash compensation (for example, Restricted Stock or Restricted Stock Units), or in which the exercise price, grant price or purchase price of the Award in the nature of a right that may be exercised is equal to the Fair Market Value of the underlying Shares minus the value of the cash compensation surrendered (for example, Options or Stock Appreciation Right granted with an exercise price or grant price "discounted" by the amount of the cash compensation surrendered), provided that any such determination to grant an Award in lieu of cash compensation must be made in compliance with Section 409A of the Code.

- (b) *Term of Awards*. The term of each Award shall be for such period as may be determined by the Committee; provided that in no event shall the term of any Option or Stock Appreciation Right exceed a period of ten years (or in the case of an Incentive Stock Option such shorter term as may be required under Section 422 of the Code).
- (c) Form and Timing of Payment Under Awards; Deferrals. Subject to the terms of the Plan and any applicable Award Agreement, payments to be made by the Company or a Related Entity upon the exercise of an Option or other Award or settlement of an Award may be made in such forms as the Committee shall determine, including, without limitation, cash, Shares, other Awards or other property, and may be made in a single payment or transfer, in installments, or on a deferred basis, provided that any determination to pay in installments or on a deferred basis shall be made by the Committee at the date of grant. Any installment or deferral provided for in the preceding sentence shall, however, be subject to the Company's compliance with applicable law and all applicable rules of the Listing Market, and in a manner intended to be exempt from or otherwise satisfy the requirements of Section 409A of the Code. Subject to Section 7(e) hereof, the settlement of any Award may be accelerated, and cash paid in lieu of Shares in connection with such settlement, in the sole discretion of the Committee or upon occurrence of one or more specified events (in addition to a Change in Control). Any such settlement shall be at a value determined by the Committee in its sole discretion, which, without limitation, may in the case of an Option or Stock Appreciation Right be limited to the amount if any by which the Fair Market Value of a Share on the settlement date exceeds the exercise or grant price. Installment or deferred payments may be required by the Committee (subject to Section 7(e) of the Plan, including the consent provisions thereof in the case of any deferral of an outstanding Award not provided for in the original Award Agreement) or permitted at the election of the Participant on terms and conditions established by the Committee. The Committee may, without limitation, make provision for the payment or crediting of a reasonable interest rate on installment or deferred payments or the grant or crediting of Dividend Equivalents o
- (d) *Exemptions from Section 16(b) Liability.* It is the intent of the Company that the grant of any Awards to or other transaction by a Participant who is subject to Section 16 of the Exchange Act shall be exempt from Section 16 pursuant to an applicable exemption (except for transactions acknowledged in writing to be non-exempt by such Participant). Accordingly, if any provision of this Plan or any Award Agreement does not comply with the requirements of Rule 16b-3 then applicable to any such transaction, such provision shall be construed or deemed amended to the extent necessary to conform to the applicable requirements of Rule 16b-3 so that such Participant shall avoid liability under Section 16(b).

## (e) Code Section 409A.

- (i) The Award Agreement for any Award that the Committee reasonably determines to constitute a Section 409A Plan, as defined in Section 7(e)(ii) hereof, and the provisions of the Plan applicable to that Award, shall be construed in a manner consistent with the applicable requirements of Section 409A, and the Committee, in its sole discretion and without the consent of any Participant, may amend any Award Agreement (and the provisions of the Plan applicable thereto) if and to the extent that the Committee determines that such amendment is necessary or appropriate to comply with the requirements of Section 409A of the Code.
- (ii) If any Award constitutes a "nonqualified deferred compensation plan" under Section 409A of the Code (a "Section 409A Plan"), then the Award shall be subject to the following additional requirements, if and to the extent required to comply with Section 409A of the Code:
  - (A) Payments under the Section 409A Plan may not be made earlier than the first to occur of (u) the Participant's "separation from service", (v) the date the Participant becomes "disabled", (w) the Participant's death, (x) a "specified time (or pursuant to a fixed schedule)" specified in the Award Agreement at the date of the deferral of such compensation, (y) a "change in the ownership or effective control of the corporation, or in the ownership of a substantial portion of the assets" of the Company, or (z) the occurrence of an "unforeseeble emergency";

- (B) The time or schedule for any payment of the deferred compensation may not be accelerated, except to the extent provided in applicable Treasury Regulations or other applicable guidance issued by the Internal Revenue Service;
- (C) Any elections with respect to the deferral of such compensation or the time and form of distribution of such deferred compensation shall comply with the requirements of Section 409A(a)(4) of the Code; and
- (D) In the case of any Participant who is "specified employee", a distribution on account of a "separation from service" may not be made before the date which is six months after the date of the Participant's "separation from service" (or, if earlier, the date of the Participant's death).

For purposes of the foregoing, the terms in quotations shall have the same meanings as those terms have for purposes of Section 409A of the Code, and the limitations set forth herein shall be applied in such manner (and only to the extent) as shall be necessary to comply with any requirements of Section 409A of the Code that are applicable to the Award.

(iii) Notwithstanding the foregoing, or any provision of this Plan or any Award Agreement, the Company does not make any representation to any Participant or Beneficiary that any Awards made pursuant to this Plan are exempt from, or satisfy, the requirements of, Section 409A, and the Company shall have no liability or other obligation to indemnify or hold harmless the Participant or any Beneficiary for any tax, additional tax, interest or penalties that the Participant or any Beneficiary may incur in the event that any provision of this Plan, or any Award Agreement, or any amendment or modification thereof, or any other action taken with respect thereto, is deemed to violate any of the requirements of Section 409A.

### 8. Code Section 162(m) Provisions.

- (a) *Covered Employees.* Unless otherwise specified by the Committee, the provisions of this Section 8 shall be applicable to any Performance Award granted to an Eligible Person who is, or is likely to be, as of the end of the tax year in which the Company would claim a tax deduction in connection with such Award, a Covered Employee.
- (b) Performance Criteria. If a Performance Award is subject to this Section 8, then the payment or distribution thereof or the lapsing of restrictions thereon and the distribution of cash, Shares or other property pursuant thereto, as applicable, shall be contingent upon achievement of one or more objective performance goals. Performance goals shall be objective and shall otherwise meet the requirements of Section 162(m) of the Code and regulations thereunder including the requirement that the level or levels of performance targeted by the Committee result in the achievement of performance goals being "substantially uncertain." One or more of the following business criteria for the Company, on a consolidated basis, and/or for Related Entities, or for business or geographical units of the Company and/or a Related Entity (except with respect to the total shareholder return and earnings per share criteria), shall be used by the Committee in establishing performance goals for such Awards: (1) earnings per share; (2) revenues or margins; (3) cash flow; (4) operating margin; (5) return on net assets, investment, capital, or equity; (6) economic value added; (7) direct contribution; (8) net income; pretax earnings; earnings before interest and taxes; earnings before interest, taxes, depreciation and amortization; earnings after interest expense and before extraordinary or special items; operating income or income from operations; income before interest income or expense, unusual items and income taxes, local, state or federal and excluding budgeted and actual bonuses which might be paid under any ongoing bonus plans of the Company; (9) working capital; (10) management of fixed costs or variable costs; (11) identification or consummation of investment opportunities or completion of specified projects in accordance with corporate business plans, including strategic mergers, acquisitions or divestitures; (12) total shareholder return; (13) debt reduction; (14) market share; (15) entry into new markets, either geographically or by business unit; (16) customer retention and satisfaction; (17) strategic plan development and implementation, including turnaround plans; and/or (18) the Fair Market Value of a Share. Any of the above goals may be determined on an absolute or relative basis or as compared to the performance of a published or special index deemed applicable by the Committee including, but not limited to, the Standard & Poor's 500 Stock Index or a group of companies that are comparable to the Company. In determining the achievement of the performance goals, unless otherwise specified by the Committee at the time the performance goals are set, the Committee shall exclude the impact of any (i) restructurings, discontinued operations, extraordinary items (as defined pursuant to generally accepted accounting principles), and other unusual or non-recurring charges; (ii) change in accounting standards required by generally accepted accounting principles; or (iii) such other exclusions or adjustments as the Committee specifies at the time the Award is granted.

- (c) *Performance Period*; *Timing For Establishing Performance Goals*. Achievement of performance goals in respect of Performance Awards shall be measured over a Performance Period specified by the Committee. Performance goals shall be established not later than 90 days after the beginning of any Performance Period applicable to such Performance Awards, or at such other date as may be required or permitted for "performance-based compensation" under Section 162(m) of the Code.
- (d) *Adjustments*. The Committee may, in its discretion, reduce the amount of a settlement otherwise to be made in connection with Awards subject to this Section 8, but may not exercise discretion to increase any such amount payable to a Covered Employee in respect of an Award subject to this Section 8. The Committee shall specify the circumstances in which such Awards shall be paid or forfeited in the event of termination of Continuous Service by the Participant prior to the end of a Performance Period or settlement of Awards.
- (e) *Committee Certification*. No Participant shall receive any payment under the Plan that is subject to this Section 8 unless the Committee has certified, by resolution or other appropriate action in writing, that the performance criteria and any other material terms previously established by the Committee or set forth in the Plan, have been satisfied to the extent necessary to qualify as "performance based compensation" under Section 162(m) of the Code.

## 9. Change in Control.

- (a) *Effect of "Change in Control."* If and only to the extent provided in any employment or other agreement between the Participant and the Company or any Related Entity, or in any Award Agreement, or to the extent otherwise determined by the Committee in its sole discretion and without any requirement that each Participant be treated consistently, upon the occurrence of a "Change in Control," as defined in Section 9(b):
  - (i) Any Option or Stock Appreciation Right that was not previously vested and exercisable as of the time of the Change in Control, shall become immediately vested and exercisable, subject to applicable restrictions set forth in Section 10(a) hereof.
  - (ii) Any restrictions, deferral of settlement, and forfeiture conditions applicable to a Restricted Stock Award, Restricted Stock Unit Award or an Other Stock-Based Award subject only to future service requirements granted under the Plan shall lapse and such Awards shall be deemed fully vested as of the time of the Change in Control, except to the extent of any waiver by the Participant and subject to applicable restrictions set forth in Section 10(a) hereof.
  - (iii) With respect to any outstanding Award subject to achievement of performance goals and conditions under the Plan, the Committee may, in its discretion, deem such performance goals and conditions as having been met as of the date of the Change in Control.
  - (iv) Notwithstanding the foregoing or any provision in any Award Agreement to the contrary, and unless the Committee otherwise determines in a specific instance or as is provided in any employment or other agreement between the Participant and the Company or any Related Entity, each outstanding Option, Stock Appreciation Right, Restricted Stock Award, Restricted Stock Unit Award or Other Stock-Based Award shall not be accelerated as described in Sections 9(a)(i), (ii) and (iii), if either (A) the Company is the surviving entity in the Change in Control and the Option, Stock Appreciation Right, Restricted Stock Award, Restricted Stock Unit Award or Other Stock-Based Award continues to be outstanding after the Change in Control on the substantially same terms and conditions as were applicable immediately prior to the Change in Control or (B) the successor company assumes or substitutes for the applicable Award, as determined in accordance with Section 10(c)(ii) hereof.

- (b) Definition of "Change in Control". A "Change in Control" shall mean the occurrence of any of the following:
- (i) The acquisition by any Person of Beneficial Ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of more than fifty percent (50%) of either (A) the value of then outstanding equity securities of the Company (the "Outstanding Company Stock") or (B) the combined voting power of the then outstanding voting securities of the Company entitled to vote generally in the election of directors (the "Outstanding Company Voting Securities") (the foregoing Beneficial Ownership hereinafter being referred to as a "Controlling Interest"); provided, however, that for purposes of this Section 9(b), the following acquisitions shall not constitute or result in a Change in Control: (w) any acquisition directly from the Company; (x) any acquisition by the Company; (y) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any Related Entity; or (z) any acquisition by any entity pursuant to a transaction which complies with clauses (A), (B) and (C) of subsection (ii) below; or
- (ii) Consummation of a reorganization, merger, statutory share exchange or consolidation or similar transaction involving the Company or any of its Related Entities, a sale or other disposition of all or substantially all of the assets of the Company, or the acquisition of assets or equity of another entity by the Company or any of its Related Entities (each a "Business Combination"), in each case, unless, following such Business Combination, (A) all or substantially all of the individuals and entities who were the Beneficial Owners, respectively, of the Outstanding Company Stock and Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than fifty percent (50%) of the value of the then outstanding equity securities and the combined voting power of the then outstanding voting securities entitled to vote generally in the election of members of the board of directors (or comparable governing body of an entity that does not have such a board), as the case may be, of the entity resulting from such Business Combination (including, without limitation, an entity which as a result of such transaction owns the Company or all or substantially all of the Company's assets either directly or through one or more subsidiaries) in substantially the same proportions as their ownership, immediately prior to such Business Combination of the Outstanding Company Stock and Outstanding Company Voting Securities, as the case may be, (B) no Person (excluding any employee benefit plan (or related trust) of the Company or such entity resulting from such Business Combination or any Person that as of the Effective Date owns Beneficial Ownership of a Controlling Interest) beneficially owns, directly or indirectly, fifty percent (50%) or more of the value of the then outstanding equity securities of the entity resulting from such Business Combination or the combined voting power of the then outstanding voting securities of such entity except to the extent that such ownership existed prior to the Business Combination and (C) at least a majority of the members of the Board of Directors or other governing body of the entity resulting from such Business Combination were members of the Incumbent Board at the time of the execution of the initial agreement, or of the action of the Board, providing for such Business Combination; or
  - (iii) Approval by the shareholders of the Company of a complete liquidation or dissolution of the Company.

## 10. General Provisions.

(a) *Compliance With Legal and Other Requirements*. The Company may, to the extent deemed necessary or advisable by the Committee, postpone the issuance or delivery of Shares or payment of other benefits under any Award until completion of such registration or qualification of such Shares or other required action under any federal or state law, rule or regulation, listing or other required action with respect to the Listing Market, or compliance with any other obligation of the Company, as the Committee, may consider appropriate, and may require any Participant to make such representations, furnish such information and comply with or be subject to such other conditions as it may consider appropriate in connection with the issuance or delivery of Shares or payment of other benefits in compliance with applicable laws, rules, and regulations, listing requirements, or other obligations.

(b) *Limits on Transferability; Beneficiaries.* No Award or other right or interest granted under the Plan shall be pledged, hypothecated or otherwise encumbered or subject to any lien, obligation or liability of such Participant to any party, or assigned or transferred by such Participant otherwise than by will or the laws of descent and distribution or to a Beneficiary upon the death of a Participant, and such Awards or rights that may be exercisable shall be exercised during the lifetime of the Participant only by the Participant or his or her guardian or legal representative, except that Awards and other rights (other than Incentive Stock Options and Stock Appreciation Rights in tandem therewith) may be transferred to one or more Beneficiaries or other transferees during the lifetime of the Participant, and may be exercised by such transferees in accordance with the terms of such Award, but only if and to the extent such transfers are permitted by the Committee pursuant to the express terms of an Award Agreement (subject to any terms and conditions which the Committee may impose thereon). A Beneficiary, transferee, or other person claiming any rights under the Plan from or through any Participant shall be subject to all terms and conditions of the Plan and any Award Agreement applicable to such Participant, except as otherwise determined by the Committee, and to any additional terms and conditions deemed necessary or appropriate by the Committee.

### (c) Adjustments.

- (i) *Adjustments to Awards*. In the event that any extraordinary dividend or other distribution (whether in the form of cash, Shares, or other property), recapitalization, forward or reverse split, reorganization, merger, consolidation, spin-off, combination, repurchase, share exchange, liquidation, dissolution or other similar corporate transaction or event affects the Shares and/or such other securities of the Company or any other issuer, then the Committee shall, in such manner as it may deem equitable, substitute, exchange or adjust any or all of (A) the number and kind of Shares which may be delivered in connection with Awards granted thereafter, (B) the number and kind of Shares by which annual per-person Award limitations are measured under Section 4 hereof, (C) the number and kind of Shares subject to or deliverable in respect of outstanding Awards, (D) the exercise price, grant price or purchase price relating to any Award and/or make provision for payment of cash or other property in respect of any outstanding Award, and (E) any other aspect of any Award that the Committee determines to be appropriate.
- (ii) Adjustments in Case of Certain Transactions. In the event of any merger, consolidation or other reorganization in which the Company does not survive, or in the event of any Change in Control, any outstanding Awards may be dealt with in accordance with any of the following approaches, without the requirement of obtaining any consent or agreement of a Participant as such, as determined by the agreement effectuating the transaction or, if and to the extent not so determined, as determined by the Committee: (a) the continuation of the outstanding Awards by the Company, if the Company is a surviving entity, (b) the assumption or substitution for, as those terms are defined below, the outstanding Awards by the surviving entity or its parent or subsidiary, (c) full exercisability or vesting and accelerated expiration of the outstanding Awards, or (d) settlement of the value of the outstanding Awards in cash or cash equivalents or other property followed by cancellation of such Awards (which value, in the case of Options or Stock Appreciation Rights, shall be measured by the amount, if any, by which the Fair Market Value of a Share exceeds the exercise or grant price of the Option or Stock Appreciation Right as of the effective date of the transaction). For the purposes of this Agreement, an Option, Stock Appreciation Right, Restricted Stock Award, Restricted Stock Unit Award or Other Stock-Based Award shall be considered assumed or substituted for if following the Change in Control the Award confers the right to purchase or receive, for each Share subject to the Option, Stock Appreciation Right, Restricted Stock Award, Restricted Stock Unit Award or Other Stock-Based Award immediately prior to the Change in Control, on substantially the same vesting and other terms and conditions as were applicable to the Award immediately prior to the Change in Control, the consideration (whether stock, cash or other securities or property) received in the transaction constituting a Change in Control by holders of Shares for each Share held on the effective date of such transaction (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding shares); provided, however, that if such consideration received in the transaction constituting a Change in Control is not solely common stock of the successor company or its parent or subsidiary, the Committee may, with the consent of the successor company or its parent or subsidiary, provide that the consideration to be received upon the exercise or vesting of an Option, Stock Appreciation Right, Restricted Stock Award, Restricted Stock Unit Award or Other Stock-Based Award, for each Share subject thereto, will be solely common stock of the successor company or its parent or subsidiary substantially equal in fair market value to the per share consideration received by holders of Shares in the transaction constituting a Change in Control. The determination of such substantial equality of value of consideration shall be made by the Committee in its sole discretion and its determination shall be conclusive and binding. The Committee shall give written notice of any proposed transaction referred to in this Section 10(c)(ii) at a reasonable period of time prior to the closing date for such transaction (which notice may be given either before or after the approval of such transaction), in order that Participants may have a reasonable period of time prior to the closing date of such transaction within which to exercise any Awards that are then exercisable (including any Awards that may become exercisable upon the closing date of such transaction). A Participant may condition his exercise of any Awards upon the consummation of the transaction.

- (iii) Other Adjustments. The Committee (and the Board if and only to the extent such authority is not required to be exercised by the Committee to comply with Section 162(m) of the Code) is authorized to make adjustments in the terms and conditions of, and the criteria included in, Awards (including Performance Awards, or performance goals and conditions relating thereto) in recognition of unusual or nonrecurring events (including, without limitation, acquisitions and dispositions of businesses and assets) affecting the Company, any Related Entity or any business unit, or the financial statements of the Company or any Related Entity, or in response to changes in applicable laws, regulations, accounting principles, tax rates and regulations or business conditions or in view of the Committee's assessment of the business strategy of the Company, any Related Entity or business unit thereof, performance of comparable organizations, economic and business conditions, personal performance of a Participant, and any other circumstances deemed relevant; provided that no such adjustment shall be authorized or made if and to the extent that such authority or the making of such adjustment would cause Options, Stock Appreciation Rights, Performance Awards granted pursuant to Section 8(b) hereof to Participants designated by the Committee as Covered Employees and intended to qualify as "performance-based compensation" under Code Section 162(m) and regulations thereunder. Adjustments permitted hereby may include, without limitation, increasing the exercise price of Options and Stock Appreciation Rights, increasing performance Awards subject to Section 8 if and to the extent that such adjustment would cause the Award to fail to qualify as "performance-based compensation" under Section 162(m) of the Code.
- (d) *Taxes.* The Company and any Related Entity are authorized to withhold from any Award granted, any payment relating to an Award under the Plan, including from a distribution of Shares, or any payroll or other payment to a Participant, amounts of withholding and other taxes due or potentially payable in connection with any transaction involving an Award, and to take such other action as the Committee may deem advisable to enable the Company or any Related Entity and Participants to satisfy obligations for the payment of withholding taxes and other tax obligations relating to any Award. This authority shall include authority to withhold or receive Shares or other property and to make cash payments in respect thereof in satisfaction of a Participant's tax obligations, either on a mandatory or elective basis in the discretion of the Committee.
- (e) Changes to the Plan and Awards. The Board may amend, alter, suspend, discontinue or terminate the Plan, or the Committee's authority to grant Awards under the Plan, without the consent of shareholders or Participants, except that any amendment or alteration to the Plan shall be subject to the approval of the Company's shareholders not later than the annual meeting next following such Board action if such shareholder approval is required by any federal or state law or regulation (including, without limitation, Rule 16b-3 or Code Section 162(m)) or the rules of the Listing Market, and the Board may otherwise, in its discretion, determine to submit other such changes to the Plan to shareholders for approval; provided that, except as otherwise permitted by the Plan or Award Agreement, without the consent of an affected Participant, no such Board action may materially and adversely affect the rights of such Participant under the terms of any previously granted and outstanding Award. The Committee may waive any conditions or rights under, or amend, alter, suspend, discontinue or terminate any Award theretofore granted and any Award Agreement relating thereto, except as otherwise provided in the Plan; provided that, except as otherwise permitted by the Plan or Award Agreement, without the consent of an affected Participant, no such Committee or the Board action may materially and adversely affect the rights of such Participant under terms of such Award.

- (f) *Limitation on Rights Conferred Under Plan.* Neither the Plan nor any action taken hereunder or under any Award shall be construed as (i) giving any Eligible Person or Participant the right to continue as an Eligible Person or Participant or in the employ or service of the Company or a Related Entity; (ii) interfering in any way with the right of the Company or a Related Entity to terminate any Eligible Person's or Participant's Continuous Service at any time, (iii) giving an Eligible Person or Participant any claim to be granted any Award under the Plan or to be treated uniformly with other Participants and Employees, or (iv) conferring on a Participant any of the rights of a shareholder of the Company including, without limitation, any right to receive dividends or distributions, any right to vote or act by written consent, any right to attend meetings of shareholders or any right to receive any information concerning the Company's business, financial condition, results of operation or prospects, unless and until such time as the Participant is duly issued Shares on the stock books of the Company in accordance with the terms of an Award. None of the Company, its officers or its directors shall have any fiduciary obligation to the Participant with respect to any Awards unless and until the Participant is duly issued Shares pursuant to the Award on the stock books of the Company in accordance with the terms of an Award. Neither the Company nor any of the Company's officers, directors, representatives or agents is granting any rights under the Plan to the Participant whatsoever, oral or written, express or implied, other than those rights expressly set forth in this Plan or the Award Agreement.
- (g) *Unfunded Status of Awards; Creation of Trusts.* The Plan is intended to constitute an "unfunded" plan for incentive and deferred compensation. With respect to any payments not yet made to a Participant or obligation to deliver Shares pursuant to an Award, nothing contained in the Plan or any Award Agreement shall give any such Participant any rights that are greater than those of a general creditor of the Company; provided that the Committee may authorize the creation of trusts and deposit therein cash, Shares, other Awards or other property, or make other arrangements to meet the Company's obligations under the Plan. Such trusts or other arrangements shall be consistent with the "unfunded" status of the Plan unless the Committee otherwise determines with the consent of each affected Participant. The trustee of such trusts may be authorized to dispose of trust assets and reinvest the proceeds in alternative investments, subject to such terms and conditions as the Committee may specify and in accordance with applicable law.
- (h) *Nonexclusivity of the Plan*. Neither the adoption of the Plan by the Board nor its submission to the shareholders of the Company for approval shall be construed as creating any limitations on the power of the Board or a committee thereof to adopt such other incentive arrangements as it may deem desirable including incentive arrangements and awards which do not qualify under Section 162(m) of the Code.
- (i) **Payments in the Event of Forfeitures; Fractional Shares.** Unless otherwise determined by the Committee, in the event of a forfeiture of an Award with respect to which a Participant paid cash or other consideration, the Participant shall be repaid the amount of such cash or other consideration. No fractional Shares shall be issued or delivered pursuant to the Plan or any Award. The Committee shall determine whether cash, other Awards or other property shall be issued or paid in lieu of such fractional shares or whether such fractional shares or any rights thereto shall be forfeited or otherwise eliminated.
- (j) *Governing Law.* The validity, construction and effect of the Plan, any rules and regulations under the Plan, and any Award Agreement shall be determined in accordance with the laws of the State of New York without giving effect to principles of conflict of laws, and applicable federal law.
- (k) *Non-U.S. Laws.* The Committee shall have the authority to adopt such modifications, procedures, and subplans as may be necessary or desirable to comply with provisions of the laws of foreign countries in which the Company or its Related Entities may operate to assure the viability of the benefits from Awards granted to Participants performing services in such countries and to meet the objectives of the Plan.
- (l) *Plan Effective Date and Shareholder Approval; Termination of Plan.* The Plan shall become effective on the Effective Date, subject to subsequent approval, within 12 months of its adoption by the Board, by shareholders of the Company eligible to vote in the election of directors, by a vote sufficient to meet the requirements of Code Sections 162(m) (if applicable) and 422, Rule 16b-3 under the Exchange Act (if applicable), applicable requirements under the rules of any stock exchange or automated quotation system on which the Shares may be listed or quoted, and other laws, regulations, and obligations of the Company applicable to the Plan. Awards may be granted subject to shareholder approval, but may not be exercised or otherwise settled in the event the shareholder approval is not obtained. The Plan shall terminate at the earliest of (a) such time as no Shares remain available for issuance under the Plan, (b) termination of this Plan by the Board, or (c) the tenth anniversary of the Effective Date. Awards outstanding upon expiration of the Plan shall remain in effect until they have been exercised or terminated, or have expired.

# CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002

### I, Daniel J. O'Connor, certify that:

- 1. I have reviewed this report on Form 10-Q for the quarter ended July 31, 2014 of Advaxis, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 8, 2014

By: /s/ Daniel J. O'Connor

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

# CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002

### I, Sara M. Bonstein, certify that:

- 1. I have reviewed this report on Form 10-Q for the quarter ended July 31, 2014 of Advaxis, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 8, 2014

By: /s / Sara M. Bonstein

Name: Sara M. Bonstein
Title: Chief Financial Officer

# CERTIFICATION-PURSUANT TO SECTION 906 OF THE SARBANES OXLEY ACT OF 2002

The undersigned as Chief Executive Officer of Advaxis, Inc. (the "Company"), does hereby certify that the foregoing Quarterly Report on Form 10-Q of the Company for the quarter ended July 31, 2014:

- (1) Fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) Fairly presents, in all material respects, the financial condition and result of operations of the Company.

September 8, 2014

/s/ Daniel J. O'Connor

Daniel J. O'Connor Chief Executive Officer

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and is not being "filed" as part of the Form 10-Q or as a separate disclosure document for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to liability under that section. This certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act except to the extent that this Exhibit 32.1 is expressly and specifically incorporated by reference in any such filing.

A signed original of this written statement required by Section 906 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.

# CERTIFICATION-PURSUANT TO SECTION 906 OF THE SARBANES OXLEY ACT OF 2002

The undersigned as Chief Financial Officer of Advaxis, Inc. (the "Company"), does hereby certify that the foregoing Quarterly Report on Form 10-Q of the Company for the quarter ended July 31, 2014:

- (1) Fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) Fairly presents, in all material respects, the financial condition and result of operations of the Company.

September 8, 2014

/s/ Sara M. Bonstein

Sara M. Bonstein Chief Financial Officer

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and is not being "filed" as part of the Form 10-Q or as a separate disclosure document for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to liability under that section. This certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act except to the extent that this Exhibit 32.1 is expressly and specifically incorporated by reference in any such filing.

A signed original of this written statement required by Section 906 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.