Form 10-K April 25, 2013
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K
ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended July 31, 2011
[] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
<u>0-11088</u>
Commission file number
TAMIR BIOTECHNOLGY, INC.
(Exact name of registrant as specified in its charter)
Delaware 22-2369085 (State or other jurisdiction of (I.R.S. Employer
incorporation or organization) Identification No.)

# 5825 Oberlin Drive, San Diego, CA (Address of principal executive offices) 92121 (Zip Code) Registrant's telephone number, including area code: (732) 823-1003 11 Deer Park Drive, Suite 204, Princeton Corporate Plaza, Monmouth Junction, NJ 08852 (Former name, former address and former fiscal year, if changed since last report) Securities registered pursuant to Section 12(b) of the Act: **None** Securities registered pursuant to Section 12(g) of the Act: None Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [] No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  $[\ ]$  No  $[\ X\ ]$ 

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [] No [X]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to

submit and post such files). Yes [] No [X]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one): Large Accelerated Filer [] Accelerated Filer [] Non-accelerated Filer [] Smaller Reporting Company [X]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act) Yes [] No [X]

The aggregate market value of the voting and non-voting common equity held by non-affiliates based upon the reported last sale price of the common stock on January 31, 2011, the end of the registrant's second fiscal quarter, was approximately \$9,338,000. As of April 25, 2013, there were 217,364,331 shares of common stock, par value \$.001 per share, outstanding.

#### **Documents Incorporated by Reference**

None

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#### **PART I**

## ITEM 1. BUSINESS.

This Annual Report on Form 10-K for the year ended July 31, 2011 contains certain "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition, liquidity and results of operations. Words such as "anticipates," "expects," "intends," "plans," "predicts," "believes," "seeks," "estimates," "could," "would," "will," "may," "can," "continue," "potential," "should, of these terms or other comparable terminology often identify forward-looking statements. Statements in this Annual Report on Form 10-K for the year ended July 31, 2011 that are not historical facts are hereby identified as "forward-looking statements" for the purpose of the safe harbor provided by Section 21E of the Exchange Act and Section 27A of the Securities Act. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in this Annual Report on Form 10-K in Item 1A under "Risk Factors" as well as in Item 7A "Quantitative and Qualitative Disclosures About Market Risk," and the risks detailed from time to time in our future Securities and Exchange Commission ("SEC") reports. These forward-looking statements include, but are not limited to, statements about:

the progress and results of our research and development programs; the failure to achieve positive results in clinical trials; the failure to obtain regulatory approval of our lead product; the ability to develop safe and efficacious drugs;

uncertainty regarding our patents and patent rights (including the risk that we may be forced to engage in costly litigation to protect such patent rights and the material harm to us if there were an unfavorable outcome of any such litigation);

our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;

the fact that we are not presently current with the filing requirements of the SEC with respect to our periodic reports; the possible delisting of our common stock and our ability to successfully regain a listing on a national securities exchange; and

uncertainty regarding the outcome of legal proceeding including the risk that we may be forced to engage in lengthy, time-consuming and expensive litigation and the material adverse effect to us of any unfavorable outcome of any such litigation.

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. Except as otherwise required by law, we do not assume any obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this Annual Report on Form 10-K or to reflect the occurrence of unanticipated events.

The following trademarks appear in this annual report on Form 10-K: ONCONASE® is the registered trademark of Tamir Biotechnology, Inc., exclusively for its anti-cancer agent, Alimta<sup>â</sup> is the registered trademark of Eli Lilly, Zolinza<sup>â</sup> is the registered trademark of Merck & Co., Avastin® is the registered trademark of Genentech and Ganciclovir® is a registered trademark of Roche.

All information in this annual report is as of April 25, 2013, unless otherwise noted and we undertake no obligation to update this information.

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#### **BUSINESS OVERVIEW**

Tamir Biotechnology, Inc. (formerly known as Alfacell Corporation) ("Tamir", "Company", "we", "us", "our", "our company" a Delaware corporation incorporated on August 24, 1981. We are a biopharmaceutical company primarily engaged in the discovery, development, and licensing of a new class of antiviral therapeutic drugs for the treatment of pathological conditions. Our proprietary drug discovery and development program consists of novel therapeutics which is being developed from amphibian ribonucleases (RNases). Since 2011, Tamir's focus has been its antiviral therapeutic drug development strategy and plan.

RNases are biologically active enzymes that are believed to be good candidates for the development of therapeutics for a variety of life-threatening diseases, including human papillomarvirus ("HPV"), cytomegalovirus ("CMV") and congenital CMV infection, human immunodeficiency virus ("HIV") and autoimmune diseases, that require anti-proliferative and apoptotic, or programmed cell death properties.

Prior to February 2011, we developed ONCONASE® (ranpirnase), a novel amphibian ribonuclease, unique among the superfamily of pancreatic ribonuclease, isolated from the eggs of the *Rana pipiens* (the northern leopard frog). Ranpirnase is the smallest known protein belonging to the superfamily of pancreatic ribonuclease and has been shown, on a molecular level, to re-regulate the unregulated growth and proliferation of cancer cells. Unlike most anti-cancer agents that attack all cells regardless of phenotype (malignant versus normal) and cause severe toxicities, ONCONASE® is not an indiscriminate cytotoxic drug (cell killing agent). ONCONASE® primarily affects exponentially growing malignant cells with activity controlled through unique and specific molecular mechanisms.

ONCONASE® was evaluated in human clinical trials for the treatment of various forms of cancer. Our most recent clinical trial for ONCONASE® was a confirmatory Phase IIIb registration trial that was designed to evaluate the efficacy, safety and tolerability of the combination of ONCONASE® and doxorubicin as compared to doxorubicin alone in the treatment of patients with unresectable (inoperable) malignant mesothelioma ("UMM"), a rare and deadly form of lung cancer. Enrollment in the Phase IIIb trial was completed in September 2007. In May 2008, we reported that the preliminary statistical analysis of data from our ONCONASE® confirmatory Phase IIIb clinical trial did not meet statistical significance for the primary endpoint of survival in UMM. However, a statistically significant improvement in survival was seen in the treatment of UMM patients who failed one prior chemotherapy regimen, a predefined primary data set for this sub-group of patients in the trial, which represents a currently unmet medical need. The United States Food and Drug Administration ("FDA"), recommended that an additional clinical trial be conducted in UMM patients that have failed one prior chemotherapy regimen, prior to filing a New Drug Application ("NDA").

February 2011, we decided to suspend the Phase II trial of ONCONASE® in combination with carboplatinum regimens in patients suffering from non-small cell lung cancer who have reached maximum progression after receiving two cycles of Alimta plus Carboplatin. Given our limited resources and based on previously reported positive *in vitro* antiviral results, we shifted our focus to the completion of *in vivo* studies for CMV, and HPV. We continue to seek financing that will be required to allow us to continue pursuing the development of ONCONASE®.

ONCONASE®, our lead drug product candidate, will be evaluated in preclinical and human clinical trials for multiple antiviral applications. Among the first targets will be the HPV and the CMV. There are over 120 HPV types that have been identified and are referred to by number. Types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 73, and 82 are carcinogenic "high-risk" sexually transmitted HPVs and may lead to the development of cervical intraepithelial neoplasia ("CIN"), vulvar intraepithelial neoplasia ("VIN"), penile intraepithelial neoplasia ("PIN"), and/or anal intraepithelial neoplasi (there are approximately 100 types, with 40 types transmitted by sexual contact). HPV is the most common of sexually-transmitted diseases known to cause genital warts, often leading to cervical or genital cancer, and recurrent respiratory papillomatosis ("RRP") which involves the growth of warts in the throat, often leading to oropharyngeal cancer. CMV is found throughout the world in all geographic and socioeconomic groups. Besides causing severe congenital infections leading to birth defects, CMV causes a wide spectrum of disorders ranging from asymptomatic, sub-clinical infections to mononucleosis syndrome in healthy individuals to life-threatening disseminated disease in immune-compromised patients.

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We believe ONCONASE®, as well as another group of our amphibian RNases, Amphinases, may also have applications in a variety of other areas in addition to those being investigated currently in our clinical development program. Amphinase is currently in the pre-clinical research and development stage.

#### MARKET OVERVIEW

With hundreds of millions of people worldwide suffering from chronic or acute viral infections, there is enormous unmet need for efficacious antiviral prophylactic and therapeutic drugs. In the past few decades researchers have begun to find ways of combating viruses, but many approaches continue to have severe and indiscriminate cell toxicity. Since viruses mutate rapidly and acquire drug resistance, the antiviral pipeline needs to be continuously replenished with new, better prophylactics and therapies. Over the next 15 years, the market will continue to expand, driven by this significant unmet need, expanding patient populations, better diagnostics and innovative new drugs, including combination therapies. In 2010, the latest date for which data is available, the market for herpes therapeutic drugs was \$4.2 billion worldwide, with an anticipated growth rate to \$9.1 billion growth rate by 2018, driven by the unmet need of viable therapeutics for immune-compromised and transplant patients. Industry observers estimate that sales for CMV therapy would top one billion dollars if there was a drug available that was both safe and effective.

HPV is the most common sexually transmitted infection ("STI"). More than 40 types of HPV are typically transmitted through sexual contact and infect the anogenital region of males and females. Some sexually transmitted HPV types may cause genital warts. There are HPV types that can infect the mouth and throat areas. Most people who become infected with HPV do not know they have it. HPV differs from herpes or HIV (the virus that causes AIDS), even though they can all be passed on during sexual intercourse.

HPV is passed on through genital contact, most often during vaginal, anal or oral sex, even when the infected partner shows no signs or symptoms.

A person can have HPV even if years have passed since he or she had sexual contact with an infected person. Most infected persons do not realize they are infected or that they are passing the virus on to a sex partner. It is also possible to get more than one type of HPV.

Very rarely, a pregnant woman with genital HPV can pass HPV to her baby during delivery. In these cases, the child can develop RRP, a rare condition in which warts grow in the throat. In children, this is also referred to as juvenile-onset recurrent respiratory papillomatosis (JORRP).

All vaccines used in the United States ("U.S.") are required to go through years of extensive safety testing before they are licensed by the FDA. Once in use, they are continually monitored for their safety and effectiveness.

Currently, there are two HPV vaccines, Gardasil and Cervarix. These vaccines are available to protect females against the two HPV types that cause most cervical cancers. The safety of Gardasil was studied in clinical trials with 29,000 females and males before it was licensed. The safety of Cervarix was studied in clinical trials with more than 30,000

females and males before it was licensed.

Both HPV vaccines are currently being monitored for any adverse events, especially rare events not identified in the study trials.

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#### Cytomegalovirus ("CMV")

CMV is one of the herpes viruses, including the herpes simplex virus, varicella-zoster virus (which causes chickenpox and shingles), and Epstein-Barr virus (which causes infectious mononucleosis, also known as mono). CMV is a common infection that is usually harmless. Once CMV is in a person's body, it stays there for life. Among every 100 adults in the U.S., 50–80 are infected with CMV by the time they are 40 years old.

Most healthy children and adults infected with CMV have no symptoms and may not even know they have been infected. Others may develop a mild illness upon infection and have the following symptoms: fever, sore throat, fatigue and swollen glands. Since these are also symptoms of other illnesses, most people do not realize they have been infected with CMV.

CMV can cause serious disease in people with a weakened immune system (See People with Weakened Immune Systems).

CMV can also cause serious disease in babies who were infected before birth (referred to as congenital CMV infection). About one in 150 children is born with congenital CMV infection, and about one of every five children born with congenital CMV infection develops permanent problems (such as hearing loss or developmental disabilities). Infants and children who are infected with CMV after birth rarely have symptoms or permanent problems (See Congenital CMV Infection for more information).

Most CMV infections are not diagnosed because CMV usually causes few, if any, symptoms, however a blood test can show whether a person has been infected.

Congenital CMV infection can be diagnosed in an infant if the virus is detected in his or her urine, saliva, or blood within 2-3 weeks after birth (See Testing and Diagnosis).

Healthy people who are infected with CMV but have no symptoms usually do not require medical treatment.

There is no drug licensed to treat congenital CMV infection. There are limited data on the use of antiviral medications in infants with symptomatic congenital CMV infection with central nervous system involvement. Pediatricians and other specialists play an important role in making sure children with congenital CMV infection are assessed and treated as needed. (See Treatment for Babies Born with CMV).

There is no available vaccine for preventing congenital CMV disease. However, a few CMV vaccines are being tested in humans, including live attenuated (weakened) virus vaccines and vaccines that contain only pieces of the virus. The Institute of Medicine has ranked the development of a CMV vaccine as a highest priority because of the lives it would save and the disabilities it would prevent. It may be a number of years before there is a FDA-approved CMV vaccine.

#### Competition

There are many companies with significantly greater resources currently marketing approved drug products, and developing new drug products designed to treat several of the viruses we may seek to treat with our products. The drug products currently marketed or developed by these companies may prove to be more effective than the products

we seek to develop.

We are not aware, however, of any product currently being marketed that has the same mechanism of action as our proposed anti-viral agent. Search of scientific literature reveals no published information that would indicate that others are currently employing this method or producing such an anti-viral agent. However, we cannot assure you others may not develop new treatments more effective than our proposed anti-viral compound.

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#### **BUSINESS STRATEGY**

Our goal is to become a leading biopharmaceutical company focused on discovering and developing innovative anti-viral treatments based on our proprietary RNase technology platform. Our strategy consists of the following key elements:

#### Focus on the Growing Anti-viral Market

In November 2009, we entered into an agreement with the National Institute of Allergy and Infectious Diseases ("NIAID") to screen our compounds (ONCONASE P31, rAmphinase 2) for its potential anti-viral activity. In July 2010, scientists supported by NIAID reported positive *in vitro* results after testing our compounds for Dengue fever and Yellow fever. According to the scientists supported by NIAID, these results have rarely been seen before. Currently, there is no therapy available to treat Dengue and Yellow fever post-infection. Further *in vitro* studies for Severe Acute Respiratory Syndrome (SARS) virus, and CMV, have also yielded positive results. In the case of CMV, a virus that is a member of the herpesvirus family, our compounds were compared to Ganciclovir, a drug marketed by Roche. Results confirmed that two of our compounds were between three and eleven times more potent than Ganciclovir in a head-to-head comparison. Moreover, our compounds did not display the level of toxicity inherent with any of the drugs approved by the FDA for CMV disease. None of the approved drugs for this indication are well tolerated by patients. Based on the results of the *in vivo* studies conducted to date, we anticipate starting proof of concept studies sometime in second quarter of 2013, and *in vivo* studies sometime in the fourth quarter of 2013. Subject to the availability of funding, further testing on other viruses is currently on-going.

## Develop our existing product portfolio

We currently have a portfolio of clinical and pre-clinical drug product candidates under development for potential use as anti-viral and other therapeutics. We intend to further develop these drug product candidates both by utilizing our internal resources and by continuing to collaborate with other companies and leading governmental and academic research institutions.

#### Commercialize Pharmaceutical Products Focused on Viral Applications in Selected Markets

Our current strategy is to partner with third parties to market our future products to virologists, and other key specialists involved in the treatment of viruses. We may also elect to develop an appropriately-sized internal sales and marketing capability in the U.S. This group may function as a standalone operation or in a supportive, co-promotion capacity in collaboration with a partner.

## **Clinical Development Program**

A Phase I and II program to evaluate a new dose and administration schedule of ONCONASE® was initiated in 2005 to attempt to take advantage of potentially increased efficacy with higher and more frequent doses of ONCONASE®. The Phase I portion of this program was completed. In 2010, we initiated a Phase II clinical trial in non-small cell lung cancer ("NSCLC") for patients who reached maximum progression after receiving two cycles of Alimta in combination with carboplatinum regimens.

At the beginning of 2011, we decided to suspend the Phase II trial of ONCONASE® in combination with carboplatinum regimens in patients suffering from non-small cell lung cancer who have reached maximum progression after receiving two cycles of Alimta plus Carboplatin. Given our limited resources and previously reported positive *in vitro* results, we shifted our focus to the completion of *in vivo* studies for CMV, and HPV. We continue to seek financing required to allow us to continue pursuing the development of ONCONASE®.

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## **Pre-Clinical Research Programs**

Our drug discovery and pre-clinical research programs form the basis for the development of specific recombinant RNases for chemically linking drugs and other compounds such as monoclonal antibodies, growth factors, etc., as well as developing gene fusion products with the goal of targeting various molecular functions. These programs provide for joint design and generation of new products with outside collaborators. Through these collaborations, we may own these new products, or grant an exclusive license to the collaborating partner(s), or both.

Novel Amphibian Ribonucleases (Amphinases)

We have also discovered a series of proteins, collectively named amphinases that may have therapeutic uses. These proteins are bioactive in that they have an effect on living cells and organisms and have both anti-cancer and anti-viral activity. All of the proteins characterized to date are RNases. Preclinical testing of the new candidates collectively called amphinases showed them to be similarly active to ranpirnase. Their chemical structure makes them ideal candidates for genetic engineering of designer products.

In September 2010, we rented a lab space for the purpose of isolating and purifying both natural and recombinant amphinases. These compounds have never undergone full screening for their potential anti-cancer and anti-viral activities. Additionally, we intend to conduct further research for conjugation of our proteins with other molecules which are known to play an important role required for targeted therapies.

These compounds have undergone screening by the NIAID against various RNA viruses and by outside collaborators. One of these compounds, AC-03-636 has been determined to be active in yellow fever, Hepatitis C and dengue fever. The same compound has been evaluated at Johns Hopkins University in a sustained time release formulation for the treatment of brain tumors, or gliomas.

Evaluation of Compounds as an Anti-Viral Agent

The ribonucleolytic activity was the basis for testing ONCONASE® as a potential anti-viral agent against HIV. The National Institute of Health ("NIH") has performed an independent *in vitro* screen of ONCONASEagainst the HIV virus type 1. The results showed ONCONASE® to inhibit replication of HIV by up to 99.9% after a four-day incubation period at concentrations not toxic to uninfected cells. *In vitro* findings by the NIH revealed that ONCONASE® significantly inhibited production of HIV in several persistently infected human cell lines, preferentially breaking down viral ribonucleic acid ("RNA") while not affecting normal cellular ribosomal RNA and

messenger RNAs, which are essential to cell function.

Moreover, the NIAID also screened ONCONASE® for anti-HIV activity. ONCONASE® demonstrated highly significant anti-HIV activity in the monocyte/macrophage, or anti-viral, system. Ranpirnase may inhibit viral replication at several points during the life cycle of HIV, including its early phases. Ranpirnase may inhibit replication of all different HIV-1 subtypes. These properties of ranpirnase are particularly relevant in view of the extremely high and exponentially increasing rate of mutations of HIV that occur during infection, and which are primarily responsible for the development of resistance to several currently available anti-viral drugs. At present, over 50% of clinical isolates of HIV are resistant to both reverse transcriptase, mechanisms which combat viral replication, and protease inhibitors drugs, a class of anti-viral drugs. An additional 25%, while being sensitive to protease inhibitors, are resistant to reverse transcriptase inhibitor drugs.

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#### **COMMERCIAL RELATIONSHIPS**

#### **License Agreements**

In January 2008, we entered into a U.S. License Agreement for ONCONASE® with Par Pharmaceutical, Inc. ("Par"). Under the terms of the License Agreement, Strativa Pharmaceuticals ("Strativa"), the proprietary products division of Par, received exclusive marketing, sales and distribution rights to ONCONASE® for the treatment of cancer in the U.S. and its territories. We retained all rights and obligations for product manufacturing, clinical development and obtaining regulatory approvals, as well as all rights for those non-U.S. jurisdictions in which we have not currently granted any such rights or obligations to third parties. We received \$5 million, fully earned, non-refundable and non-creditable, upon the signing of the License Agreement and were entitled to additional development and sales milestone payments and double-digit royalties on net sales of ONCONASE®.

On September 8, 2009, we entered into a Termination and Mutual Release Agreement (the "Termination Agreement") with Par pursuant to which our License Agreement and Supply Agreement with Par were terminated. The License Agreement was terminated and all rights under the license granted to Par reverted back to us under the Termination Agreement. Under the Supply Agreement, we had agreed to supply all of Par's requirements for ONCONASE®. Pursuant to the Termination Agreement, Par is entitled to a royalty of 2% of net sales of ONCONASE® or any other ranpirnase product developed by us for use in the treatment of cancer in the U.S. and its territories commencing with the first sale of such product and terminating upon the later to occur of the 12th anniversary of the first sale and the date of expiration of the last valid claim of a pending application or issued patent owned or controlled by us with respect to such product.

## **Marketing and Distribution Agreements**

#### Megapharm Ltd.

In May 2008, we entered into an exclusive marketing, sales and distribution agreement with Megapharm Ltd. ("Megapharm") for the commercialization of ONCONASE In Israel. Under the agreement, we are eligible to receive 50% of net sales in the territory. We will be responsible for the manufacture and supply of ONCONASE® to Megapharm, while Megapharm will be responsible for all activities and costs related to regulatory filings and commercial activities in the territory.

## BL&H Co. Ltd.

In January 2008, we entered into a marketing and distribution agreement with BL&H Co. Ltd. ("BL&H") for the commercialization of ONCONASE® in Korea, Taiwan and Hong Kong. Under the agreement, we received a \$100,000 up-front fee and are eligible to receive additional cash milestones and 50% of net sales in the territory. We will be responsible for the manufacture and supply of ONCONASE® to BL&H, while BL&H will be responsible for all activities and costs related to regulatory filings and commercial activities in the territory.

#### US Pharmacia

In July 2007, we entered into a Distribution and Marketing Agreement (the "Distribution Agreement"), with USP Pharma Spolka Z.O.O. (the "Distributor"), an affiliate of US Pharmacia, pursuant to which the Distributor was granted exclusive rights for the marketing, sales, and distribution of ONCONASE® for use in oncology in Poland, Belarus, Ukraine, Estonia, Latvia, and Lithuania (the "Territory") for an initial term that ends upon the earlier of (i) 10 years from the first commercial sale in the Territory and (ii) the date all of the patents covering the product in the Territory expire. We received an up-front payment of \$100,000 and are entitled to receive milestone payments based on the achievement of certain regulatory approvals and certain sales goals. In addition, we will receive a royalty on net sales as well as a transfer price for product sold to the Distributor. We will be responsible for making regulatory filings and seeking marketing approval of ONCONASE® in the Territory and manufacturing and supplying ONCONASE® to the Distributor. The Distributor will be responsible for all commercial activities and related costs in the Territory.

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In connection with the Distribution Agreement, we also entered into a Securities Purchase Agreement, with Unilab LP, an affiliate of US Pharmacia, pursuant to which we issued 553,360 shares of restricted common stock for \$1.4 million, or \$2.53 per share.

On November 23, 2011, Tamir entered into a Memorandum of Understanding ("MOU"), with US Pharmacia, hereafter (USPI and/or affiliates), pursuant to which USPI, will be granted the exclusive marketing, sales, and distribution rights of ONCONASE® for use in Human Papillioma Virus (HPV) in the European Territory upon completion of full License payment. Territory includes Western and Eastern Europe. USPI was to pay Tamir the sum of \$1 million in installments provided Tamir achieves certain milestones. Under the MOU, on December 12, 2011, Tamir received an initial payment of \$405,000 and Tamir provided USPI with Proof of Concept ("POC") demonstrating successful formulation drug formulation of ONCONASE® which will be used to treat genital and skin warts caused by the HPV and *in vivo* penetration of ONCONASE® into the skin. Tamir provided this POC by March 31, 2011. USPI has agreed to make a \$95,000 milestone payment to Tamir, for the completion of a topical formulation and initiation of testing of ONCONASE® in the HPV Proof of Concept study. On June 13, 2012, Tamir received initial results from the independent laboratory performing the ongoing non-clinical proof-of-concept study of ONCONASE® as a potential HPV. Once other pre-clinical milestones are met USPI shall pay Tamir the balance of \$500,000 in installments.

#### GENESIS Pharma S.A.

In December 2006, we entered into a Distribution and Marketing Agreement with GENESIS Pharma S.A. ("GENESIS"), pursuant to which GENESIS was granted exclusive rights for the marketing, sales, and distribution of ONCONASE® for use in oncology in Greece, Cyprus, Bulgaria, Romania, Slovenia, Croatia, Serbia and Macedonia (the "Region") for an initial term that ends upon the earlier of (i) 10 years from the first commercial sale in the Region and (ii) the date all of the patents covering the product in the Region expire. We will retain ownership of all intellectual property relating to ONCONASE® and responsibility for all regulatory filings with Europe, Middle East and Africa ("EMEA"), in the European Union ("EU"), with GENESIS providing assistance with regard to regulatory filings in the non-EU countries included in this agreement. We will also be responsible for manufacturing and supplying the product to GENESIS, which will distribute the product. GENESIS will have lead responsibility for all ONCONASE® commercialization activities and will manage all operational aspects of the marketing, sales and distribution of the product in the Region. We are entitled to receive milestone payments based on the achievement of certain regulatory approvals and certain sales goals. In addition, we will receive a royalty on net sales as well as a transfer price for product sold by us to GENESIS.

Manufacturing

In January 2008, we entered into a Purchase and Supply Agreement (the "Supply Agreement") with Scientific Protein Laboratories LLC ("SPL"). Under the Supply Agreement, SPL will manufacture and be our exclusive supplier for the commercial bulk drug substance used to make ONCONASE®. The term of the Supply Agreement is 10 years and we have the right to terminate the Supply Agreement at any time without cause with two years prior notice to SPL.

Additionally, in fiscal 2011, we contracted with Ben Venue Laboratories Inc. ("Ben Venue") for vial filling and with Bilcare Global Clinical Supplies, Americas ("Bilcare"), Aptuit, Inc. ("Aptuit") and Catalent Pharma Solutions, Inc. ("Catalent") for the labeling, storage and shipping of ONCONASE for use in clinical trials. This contract was terminated by Ben Venue in February 2012. We have no other arrangements for the manufacture of ONCONASE.

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Products manufactured for use in clinical trials and for commercial sale must be manufactured in compliance with Current Good Manufacturing Practices ("CGMP"). SPL, Ben Venue, Aptuit and Catalent are all licensed or approved by the appropriate regulatory agencies and all work is performed in accordance with CGMP. For the foreseeable future, we intend to rely on these manufacturers and related service providers, or substitute vendors, if necessary, to manufacture our product. We believe, however, there are substantial alternative providers for the services for which we contract. For those relationships where we have not entered into formal agreements, we utilize the services of these third party contractors solely on an as needed basis with prices and terms customary for companies in businesses that are similarly situated. In order to replace an existing manufacturer, we must amend our Investigational New Drug application to notify the appropriate regulatory agencies of the change. We are dependent upon our contract manufacturers to comply with CGMP and to meet our production requirements. It is possible that our contract manufacturers may not comply with CGMP or deliver sufficient quantities of our products on schedule, or that we may be unable to find suitable and cost effective alternative providers if necessary.

#### **Raw Materials**

The major active ingredient derived from leopard frog eggs is the protein ranpirnase. We believe we have sufficient egg inventory on hand to produce enough ONCONASE® for our future clinical trials and early commercialization. In addition, we have successfully produced ranpirnase in small proof-of-concept size batches using recombinant technology. However, this technology requires additional testing and FDA approval and it may be determined to not be more cost effective than current methods of production.

Patents and Proprietary Technology

We have sought to protect our technology by applying for, and obtaining, patents and trademark registrations. We have also relied on trade secrets and know-how to protect our proprietary technology. We continue to develop our portfolio of patents, trade secrets, and know how. We have obtained, and continue to apply for, patents concerning our RNase-based technology.

In addition, we have filed (and we intend to continue to file) foreign counterparts to certain U.S. patent applications. Generally, we apply for patent protection in the U.S.

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# We own the following U.S. patents:

Patent No.	<u>Issue</u> <u>Date</u>	Subject Matter	Expiration **
5,529,775	June 1996	covers combinations of ONCONASE® with certain other pharmaceuticals	June 2013
5,728,805	Mar. 1998	covers a family of variants of ONCONASE®	June 2013
5,540,925	July 1996	covers combinations of ONCONASE® with certain other pharmaceuticals	July 2013
5,559,212	Sept. 1996	covers the amino acid sequence of ONCONASE®	Sept. 2013
5,595,734	Jan. 1997	covers combinations of ONCONASE® with certain other pharmaceuticals	Jan. 2014
6,649,392 B1*	Nov. 2003	covers a family of recombinant variants of ONCONASE®	Apr. 2016
6,649,393 B1*	Nov. 2003	covers nucleic acids encoding recombinant variants of ONCONASE® and methodology for producing such variants	Apr. 2016
6,290,951 B	1 Sept. 2001	covers alteration of the cell cycle <i>in vivo</i> , particularly for inducing apoptosis of tumor cells	Aug. 2018
6,239,257 B	1 May 2001	covers a family of variants of ONCONASE®	Dec. 2018
6,175,003 B	1 Jan. 2001	covers the genes of ONCONASE® and a variant of ONCONASE®	Sept. 2019
6,423,515 B	1 July 2002	covers methodology for synthesizing gene sequences of ONCONASE® and a genetically engineered variant of ONCONASE®	Sept. 2019
7,229,824 B1***	June 2007	covers a vector containing DNA encoding a genetically engineered Amphinase	May 2024
7,556,952 B2	<sup>2</sup> July 2009	covers a gene encoding a genetically engineered Amphinase	July 2023
7,556,951 B2	2 July 2009	covers a gene encoding a genetically engineeredAmphinase, and a vector containing DNA encoding a genetically engineered Amphinase	July 2023
7,556,953 B2	2 July 2009	covers a gene encoding a genetically engineered Amphinase, and a vector containing DNA encoding a genetically engineered Amphinase	July 2023
7,442,535 B2	Oct. 2008	covers a fusion protein containing a genetically engineered Amphinase	July 2023
7,585,655 B2		covers a gene encoding a genetically engineered Amphinase, and a vector containing DNA encoding it	July 2023
7,442,536 B2	Oct. 2008	covers genetically engineered Amphinases	July 2023
7,585,654 B2	Sept. 2009	covers a vector containing DNA encoding a genetically engineered Amphinase, and a gene encoding a genetically engineered Amphinase	July 2023
7,473,542 B2	2 Jan. 2009	Covers a fusion protein containing a genetically engineered Amphinase	July 2023
7,763,449 B2			July 2023

July covers a vector containing DNA encoding a genetically engineered Amphinase, 2010 and a gene encoding a genetically engineered Amphinase

\*We own this patent jointly with the U.S. Government. We do not pay maintenance fees to keep this patent in force.

Tamir now uses the term "Amphinase" to describe a family of proteins. ONCONASE and proteins in the Amphinase family, belong to the same superfamily of Ribonucleases. Amphinase proteins were previously referred to as "variants" of ONCONASE®.

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We own the following foreign patents in Europe (European patents are validated in selected European nations) and Japan:

Patent No.

Subject Matter Expiration \*\*

EP 0 656 783

covers combinations of ONCONASE<sup>â</sup> with certain other pharmaceuticals July 2013

JP 3655628 EP 0 837 878

covers a variant of ONCONASE<sup>â</sup> and a method of producing it June 2016

JP 3779999 EP 1 141 004

covers a family of variants of ONCONASE® Dec. 2019

JP 4516216

We also have patent applications pending in the U.S., Europe, Japan, and other foreign countries.

The scope of protection afforded by patents for biotechnological inventions can be uncertain, and such uncertainty may apply to our patents as well. The patent applications we have filed, or that we may file in the future, may not issue as patents. Our patents may not give us a competitive advantage, may be wholly or partially invalidated or held unenforceable, or may be held not to have been infringed by products that compete with our products. Patents owned by others may adversely affect our ability to do business. Furthermore, others may independently develop products that are similar to our products or that duplicate our products, and may design around the claims of our patents. Although we believe U.S. patents and patent applications are of substantial value to us, we cannot assure you such patents and patent applications will be of commercial benefit to us, will adequately protect us from competing products or will not be challenged, declared invalid, or found not to have been infringed by competing products. We also rely on proprietary know-how and on trade secrets to develop and maintain our competitive position. Others may independently develop or obtain access to such know-how or trade secrets. Although our employees and consultants having access to proprietary information are required to sign agreements that require them to keep such information confidential, our employees or consultants may breach these agreements or these agreements may be held to be unenforceable.

<sup>\*\*</sup>Assumes timely payment of all applicable maintenance fees and annuities; excludes term extensions that do or may apply.

<sup>\*\*\*</sup>Includes a term extension of 312 days under 35 U.S.C. §154(b).

In the future, others may file patent applications covering technologies that we may wish to utilize with our proprietary technologies, or products that are similar to products developed with the use of our technologies. If these patent applications result in issued patents and we wish to use the claimed technology, we would need to obtain a license from the third party, and this would increase our costs of operations which could harm our operating results.

## Government Regulation

The manufacturing and marketing of pharmaceutical products in the U.S. require the approval of the FDA under the Federal Food, Drug and Cosmetic Act. Similar approvals by comparable regulatory agencies are required in most foreign countries. The FDA has established mandatory procedures and safety standards that apply to the clinical testing, manufacturing and marketing of pharmaceutical products in the U.S. Obtaining FDA approval for a new therapeutic drug may take many years and involve substantial expenditures. State, local and other authorities also regulate pharmaceutical manufacturing facilities.

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As the initial step in the FDA regulatory approval process, preclinical studies are conducted in analytical laboratory settings -in cell-line models, and in animal models to assess the drug's potential drug effect and to measure how much of a drug is absorbed into the blood, how it is broken down chemically in the body, the toxicity of the drug and its breakdown products (metabolites), and how quickly the drug and its metabolites are excreted from the body. Preclinical testing can also be used to identify potential safety problems. Moreover manufacturing processes and controls for the product are required. The manufacturing information along with the results of these studies is submitted to the FDA as part of the Investigational New Drug Application ("IND"), which is filed to obtain approval to begin human clinical testing. The human clinical testing program typically involves up to three phases. Data from human trials as well as other regulatory requirements such as chemistry, manufacturing and controls, pharmacology and toxicology sections, are submitted to the FDA in an NDA or Biologics License Application ("BLA"). Preparing an NDA or BLA involves considerable data collection, verification and analysis. A similar process in accordance with EMEA regulations in Europe and with TGA regulations in Australia is required to gain marketing approval. Moreover, a commercial entity must be established and approved by the EMEA in a member state of the EU at least three months prior to filing the Marketing Authorization Application ("MAA").

We have not received U.S. or other marketing approval for any of our product candidates and may not receive any approvals. We may encounter difficulties or unanticipated costs in our effort to secure necessary governmental approvals, which could delay or preclude us from marketing our products.

With respect to patented products, delays imposed by the governmental approval process may materially reduce the period during which we may have the exclusive right to exploit them.

#### **Environmental Matters**

Our operations are subject to comprehensive regulation with respect to environmental, safety and similar matters by the U.S. Environmental Protection Agency and similar state and local agencies. Failure to comply with applicable laws, regulations and permits can result in injunctive actions, damages and civil and criminal penalties. If we expand or change our existing operations or propose any new operations, we may need to obtain additional or amend existing permits or authorizations. We spend time, effort and funds in operating our facilities to ensure compliance with environmental and other regulatory requirements.

Such efforts and expenditures are common throughout the biotechnology industry and generally should have no material adverse effect on our financial condition. The principal environmental regulatory requirements and matters known to us requiring or potentially requiring capital expenditures by us do not appear likely, individually or in the aggregate, to have a material adverse effect on our financial condition.

**Employees** 

As of July 31, 2011, we had two part-time employees, of whom one was engaged in clinical and pre-clinical research and development activities and the other was engaged in administration and management. All of our employees have entered into confidentiality agreements with us. None of our employees are covered by a collective bargaining agreement.

#### **Available Information**

We electronically file our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports with the SEC. These and other SEC reports filed by us are available to the public at the SEC's website at www.sec.gov. You may read and copy any document we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room. Additionally, we have also adopted a Code of Business Conduct and Ethics applicable to all officers, directors, and employees. Copies are also available without charge upon request.

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#### Item 1A. RISK FACTORS.

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors and all other information contained in this annual report on Form 10-K before purchasing shares of our common stock. If any of the following risks occur, our business, financial condition and/or results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

#### RISKS RELATED TO OUR BUSINESS

We will need additional funding to support our operations and capital expenditures. Such funds may not be available to us, which lack of availability could reduce our research and development activities and future business prospects.

While we have historically funded our working capital needs through the sale of equity and debt interests and capital contributions from related parties, we will need to obtain significant additional funding to continue our planned operations, pursue business opportunities, react to unforeseen difficulties and/or respond to competitive pressures. Our latest private placement financing transaction raised about \$1 million in December, 2012 which will allow us to continue to devote significant efforts to developing the necessary compounds and supplies to be used in additional testing of our formulations as well as continuing corporate obligations. We estimate the net funds from this private placement transaction will be sufficient to fund our planned activities through September 30, 2013.

While we need to raise significant additional funds, we currently have no committed sources of additional capital, and there can be no assurance that any financing arrangements will be available in amounts or on terms acceptable to us, if at all. Furthermore, the sale of additional equity or convertible debt securities may result in additional dilution to existing stockholders. If adequate additional funds are not available, we may be required to delay, reduce the scope of or eliminate material parts of the implementation of our business strategy. This limitation would impede our growth and could result in a contraction of our operations, which would reduce our research and development activities and future business prospects.

We may be unable to continue as a going concern if we do not successfully raise additional capital.

If we are unable to successfully raise the capital we need, we may need to reduce the scope of our business to fully satisfy our future short-term liquidity requirements. If we cannot raise additional capital or reduce the scope of our

business, we may be otherwise unable to achieve our goals or continue our operations. We have incurred losses from operations in the prior two years and have a lack of liquidity. These factors raise substantial doubt about our ability to continue as a going concern. In addition, our auditors have included in their report on our audited financial statements an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern. While we believe that we will be able to raise the capital we need to continue our operations, there can be no assurances that we will be successful in these efforts or will be able to resolve our liquidity issues or eliminate our operating losses.

We have a history of operating losses and there can be no assurance that we can achieve or maintain profitability.

We have a history of operating losses and may not achieve or sustain profitability. Even if we achieve profitability, given the competitive and evolving nature of the industry in which we operate, we may not be able to sustain or increase profitability and our failure to do so would adversely affect our business, including our ability to raise additional funds.

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Our proprietary technology and patents may offer only limited protection against infringement and the development by our competitors of competitive products.

We own two patents jointly with the United States government. These patents expire in 2016. We also own 18 United States patents with expiration dates ranging from 2013 to 2024, three European patents with expiration dates ranging from 2013 to 2019, and three Japanese patents with expiration dates ranging from 2013 to 2019. The scope of protection afforded by patents for biotechnological inventions is uncertain, and such uncertainty applies to our patents as well. Therefore, our patents may not give us competitive advantages or afford us adequate protection from competing products. Intellectual property litigation, including patent litigation, is expensive and our resources are limited. To date, we have not received any threats of litigation regarding patent issues. However, if we were to become involved in litigation, we might not have the funds or other resources necessary to conduct the litigation effectively. This might prevent us from protecting our patents, from defending against claims of infringement, or both.

We may be sued for infringing on the intellectual property rights of others.

Our commercial success also depends in part on not infringing upon the patents or proprietary rights of third parties. The biotechnology industry has produced a proliferation of patents, and the scope of protection afforded by those patents is not always clear. The scope of protection afforded by a patent is determine by the court in which the infringement action is tried, and such determinations are not always consistent. While we have not been sued for infringing the intellectual property rights of others, there can be no assurance that products and methods we have under development do not or will not infringe on the patent or proprietary rights of others. Third parties may assert that we are employing their proprietary technology without authorization. Although United States patent applications filed in recent years are published 18 months after filing, older applications are not published until they issue as patents. Further, in some circumstances, publication of even recently-filed patent applications may not occur. As a result, we may not be aware of a patent until it issues and the owner asserts it against us, making it difficult to proactively avoid patent infringement. If we are sued for patent infringement, we may need to demonstrate that the patent claims are invalid, which we may not be able to do. Proving such invalidity is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Parties making claims against us may be able to obtain injunctive or other equitable relief that could effectively block our ability to further develop, commercialize and sell products, and such claims could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may also need to obtain license rights from the plaintiff(s). We may not be able to obtain such license rights at a reasonable cost, or at all. In that event, we could encounter delays in product introductions while we attempt to develop alternative methods or products or be required to cease commercializing affected products and our operating results would be harmed.

In the future, others may file patent applications covering technologies that we may wish to utilize with our proprietary technologies, or products that are similar to products developed with the use of our technologies. If these patent applications result in issued patents and we wish to use the claimed technology, we would need to obtain a license from the third party, and this would increase our costs of operations and harm our operating results

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We and our licensees will be subject to federal and state regulation. Our inability to comply with these regulations would cause us to curtail or cease our operating activities, which would result in a reduction in revenue and harm our business, operating results and financial condition.

We and our potential licensing partners are subject to many laws and regulations, and any adverse regulatory action may affect our ability to exploit our IP. Developing, manufacturing, and marketing regulated medical products and pharmaceuticals are subject to extensive and rigorous regulation by numerous government and regulatory agencies, including the FDA and comparable foreign agencies. Under the Federal Food, Drug, and Cosmetic Act (the "FDA Act"), regulated medical devices must receive FDA clearance and approval before they can be commercially marketed in the U.S. Markets outside the U.S. require similar clearance and approval before a medical product or pharmaceutical can be commercially marketed. We cannot guarantee that the FDA or other regulatory authorities will accept any IND applications we may file or that such authorities will not delay consideration of accepted applications. We also cannot guarantee that we will be able to agree on matters raised during the regulatory review process or obtain, directly or through our licensees, marketing clearance from the FDA and other governing agencies for any new products, or modifications or enhancements to existing products, which we depend on for royalty revenues. Furthermore, if FDA clearance is obtained, such clearance could (i) take a significant amount of time; (ii) require the expenditure of substantial resources; (iii) involve rigorous pre-clinical and clinical testing; (iv) require significant modifications to, or replacements of, products; and/or (v) result in limitations on the proposed uses of products.

Even after regulated medical products or pharmaceuticals have received marketing clearance, approvals by the FDA can be withdrawn due to failure to comply with regulatory standards or the occurrence of unforeseen issues following initial approval. Failure to comply with regulatory standards or subsequent discovery of unknown problems with a regulated medical product could result in fines, suspensions of regulatory approvals, seizures or recalls of devices, operating restrictions, and/or criminal prosecution. There can be no assurance that FDA approval will not be subsequently withdrawn. Any adverse regulatory action by the FDA or another regulatory agency may restrict us and our licensees from effectively marketing and selling our intellectual property ("IP") applications in medical products, resulting in a reduction in revenue and harm to our business, operating results and financial condition. In addition, foreign laws and regulations have become more stringent and regulated medical products may become subject to increased regulation by foreign agencies in the future. Penalties for our licensees for any of their noncompliance with foreign governmental regulations could be severe, including revocation or suspension of their business licenses and criminal sanctions. Any foreign law or regulation imposed on our IP applications may materially affect our projected operations and revenues, by adversely impacting the distribution and sale of regulated medical products in foreign jurisdictions through our intended licensees.

We depend on third parties for testing the product candidates we intend to develop. Any failure of those parties to perform as expected or required could adversely affect our product development and commercialization plans.

We have used and intend to continue to use various types of collaborative arrangements with commercial and academic entities as vehicles for testing compounds and molecules for our future product candidates. Our research

arrangements and any other similar relationships we may establish may not proceed on the expected timetable, or our collaborators may not perform as expected or required under their agreements with us. The research performed under such collaborations and arrangements may not provide results that are satisfactory for regulatory approval of products containing our compounds or molecules. If our research and commercial relationships fail to yield product candidates that we can take into development, such failure will delay or prevent our ability to commercialize products.

In addition, we rely on third parties such as contract laboratories and clinical research organizations to conduct, supervise or monitor, some or all aspects of the preclinical studies and clinical trials for our product candidates, and we have limited ability to control many aspects of their activities. Accordingly, we have less control over the timing and other aspects of those clinical trials than if we conducted them on our own. Third-party contractors may not complete activities on schedule, or may not conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our trial design. The failure of these third parties to perform their obligations could delay or prevent the development, approval and commercialization of our product candidates.

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Future developments in technology or future pharmacological compounds may make the products we are planning to bring to market obsolete, with a consequent negative impact on our profitability.

We believe the methods for treating and preventing we intend to bring to market enjoy certain competitive advantages, including superior performance and cost-effectiveness. Although we are not aware of other treatments or methods currently being developed that would compete with the methods we intend to employ, there can be no assurance that future developments in technology or compounds will not make our technology non-competitive or obsolete, or significantly reduce our operating margins or the demand for our offerings, or otherwise negatively impact our profitability.

Intellectual property litigation would be costly and could adversely impact our business operations.

We may have to take legal action in the future to protect our technology or to assert our IP rights against others. Any legal action could be costly and time consuming to us and no assurances can be made that any action will be successful. The invalidation of any patent or IP rights that we may own, or an unsuccessful outcome in lawsuits to protect our technology, could have a material adverse effect on our business, financial position, or results of operations.

We operate and compete in an industry that is characterized by extensive IP litigation. In recent years, it has been common for companies in the medical product and pharmaceutical businesses to aggressively file patent-infringement and other intellectual-property litigation in order to prevent the marketing of new or improved medical products, treatments, or pharmaceuticals. IP litigation can be expensive, complex, and protracted. Because of such complexity, and the vagaries of the jury system, IP litigation may result in significant damage awards and/or injunctions that could prevent the manufacture, use, distribution, importation, exportation, and sale of products or require us and/or any of our licensing partners to pay royalties to continue to manufacture, use, distribute, import, export, or sell products. Furthermore, in the event that our right to license or to market our technology is successfully challenged, and if we and/or our licensing partners fail to obtain a required license or are unable to design around a patent held by a third party, our business, financial condition, or results of operations could be materially adversely affected. We believe that the patents we have applied for, if granted, would provide valuable protection for our intellectual property, but there nevertheless could be no assurances that they would be respected or not subject to infringement by others.

Product safety and product liability claims and litigation would be costly and adversely impact our financial condition.

Our pharmaceutical compounds will have known side effects and could have significant side effects that are not identified during the research and approval phases. If patients are affected by known or unknown side effects, related claims may exceed insurance coverage and materially and adversely impact our financial condition.

Our industry is highly competitive and we have less capital and resources than many of our competitors, which may give them an advantage in developing and marketing products similar to ours or make our products obsolete.

We are engaged in highly competitive fields of pharmaceutical research and development. Competition from numerous existing companies and others entering the fields in which we operate is intense and expected to increase. We expect to compete with, among others, conventional pharmaceutical companies. Most of these companies have substantially greater research and development, manufacturing, marketing, financial, technological personnel and managerial resources than we do. Acquisitions of competing companies by large pharmaceutical or health care companies could further enhance such competitors' financial, marketing and other resources. Moreover, competitors that are able to complete clinical trials, obtain required regulatory approvals and commence commercial sales of their products before we do may enjoy a significant competitive advantage over us. There are also existing therapies that may compete with the products we are developing. There can be no assurance we will be able to successfully compete against these other entities.

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If we do not establish strategic partnerships to commercialize our products under development, we will have to undertake commercialization efforts on our own, which could be costly and may ultimately be unsuccessful.

We may selectively partner with other companies to obtain assistance for the commercialization of certain of our products. We may enter into strategic partnerships with third parties to develop and commercialize some of our products that are intended for larger markets or that otherwise require a large, specialized sales and marketing organization, and we may enter into strategic partnerships for products that are targeted beyond our selected target markets. We face competition in seeking appropriate strategic partners, and these strategic partnerships can be intricate and time consuming to negotiate and document. We may not be able to negotiate strategic partnerships on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any strategic partnerships because of the numerous risks and uncertainties associated with establishing strategic partnerships. If we are unable to negotiate strategic partnerships for our products under development, we may be forced to reduce the scope of our anticipated sales or marketing activities or undertake commercialization activities at our own expense. In addition, we will bear the entire risk related to the commercialization of these products. If we elect to increase our expenditures to fund commercialization activities on our own, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all.

If our licensees fail to sustain compliance with regulatory standards and laws applicable to medical products production, manufacturing and quality processes, the marketing of our products could be suspended, and such suspension could, for our licensees, lead to fines, withdrawal of regulatory clearances, product recalls, or other consequences, any of which could in turn adversely affect our projected business operations, financial condition, or results of operations.

Our licensees, which will be manufacturers of medical products or pharmaceuticals, will be subject to periodic inspection by the FDA for compliance with regulations that require manufacturers to comply with certain practices and standards, including testing, quality control and documentation procedures. In addition, federal medical device reporting regulations will require them to provide information to the FDA whenever there is evidence that reasonably suggests that a medical product may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. Compliance with these requirements is subject to continual review and is rigorously monitored through periodic FDA inspections. In foreign markets, our licensing partners will be required to obtain certain certifications to sell medical products and will have to undergo periodic inspections by regulatory bodies to maintain these certifications. If our licensees fail to adhere to any laws and standards applicable to medical product manufacturers, the marketing of products could be suspended, and such failure could, for our licensees, lead to fines and withdrawal of regulatory clearances, product recalls, or other consequences, any of which could in turn adversely affect our projected business operations, financial condition, or results of operations. Our licensees will also be subject to certain environmental laws and regulations. Our licensing partners' manufacturing operations may involve the use of substances and materials regulated by various environmental protection agencies and regulatory bodies. We cannot guarantee that any licensee will sustain compliance with environmental laws, and that regulations will not have a material impact on our earnings, financial condition, or business operations.

Quality problems with a licensee's manufacturing processes could harm our reputation and affect demand for medical products using our technology.

Ensuring the quality of products and manufacturing processes is critical for medical product companies due to the high cost and seriousness of product failures or malfunctions. If any of our licensees failed to meet adequate quality standards, its and our reputations could be damaged and our revenues would decline. In addition, production of medical products which utilize our technology may depend on our licensees' abilities to engineer and manufacture precision components and assemble such components into intricate medical products. We cannot guarantee that our licensees or third-party suppliers will not encounter problems or delays in timely manufacturing or assembling our products and other materials related to the manufacture or assembly of our products, or in manufacturing our products in amounts sufficient to support our development and commercialization efforts. If our licensees fail to meet these requirements or fail to adapt to changing requirements, their and our reputations may suffer and demand for products implementing our technology would decline significantly.

#### Uncertainties regarding healthcare reimbursements may adversely affect our business.

Healthcare cost containment pressures decrease the prices end-users are willing to pay for medical products, which could have an adverse effect on our royalty revenue. Products that may implement our technology may be purchased by hospitals or physicians, which typically bill governmental programs, private insurance plans and managed care plans for the healthcare devices and services provided to their patients. The ability of these customers to obtain reimbursement from private and governmental third-party payors for the products and services they provide to patients is critical to commercial success. The availability of reimbursement affects which products customers purchase and the prices they are willing to pay. Reimbursement varies from country to country and can significantly impact the acceptance of new products and services. Although we and our licensees may have a promising new product, we and our licensees may find limited demand for the product unless reimbursement approval is obtained from private and governmental third-party payors. Even if reimbursement approval is obtained from private and governmental third-party payors, we may still find limited demand for the product for other reasons. In addition, legislative or administrative reforms to the U.S., or to international reimbursement systems, in a manner that significantly reduces reimbursement for products or procedures using our technology, or denial of coverage for those products or procedures, could have a material adverse effect on our business, financial condition or results of operations.

Major third-party payors for hospital services in the U.S. and abroad continue to work to contain healthcare costs. The introduction of cost containment incentives, combined with closer scrutiny of healthcare expenditures by both private health insurers and employers, has resulted in increased discounts and a contractual adjustment to hospital charges for services performed and has shifted services between inpatient and outpatient settings. Initiatives to limit the increase of healthcare costs, including price regulation, are also ongoing in markets in which our licensees may do business. Hospitals or physicians may respond to these cost-containment pressures by insisting that our licensees lower prices, which may adversely affect our royalties.

In response to increasing healthcare costs, there has been and may continue to be proposals by legislators, regulators, and third-party payers to reduce these costs. If these proposals are passed, limitations and/or reductions may be placed on the net or allowable price of products implementing our technology or the amounts of reimbursement available for these products from customers, governmental bodies, and third-party payors. These limitations and reductions on prices may have a material adverse effect on our financial position and results of operations.

Our forecasts are highly speculative in nature and we cannot predict results with a high degree of accuracy.

Any financial projections, especially those based on ventures with minimal operating history, are inherently subject to a high degree of uncertainty, and their ultimate achievement depends on the timing and occurrence of a complex series of future events, both internal and external to the enterprise. There can be no assurance that potential revenues or expenses we project will, in fact, be received or incurred.

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We will be subject to evolving and expensive corporate governance regulations and requirements. Our failure to adequately adhere to these requirements or the failure or circumvention of our controls and procedures could seriously harm our business.

As a publicly traded company, we are subject to various federal, state and other rules and regulations, including applicable requirements of the Sarbanes-Oxley Act of 2002. Compliance with these regulations is costly and requires a significant diversion of management time and attention, particularly with regard to our disclosure controls and procedures and our internal control over financial reporting. Our internal controls and procedures may not be able to prevent errors or fraud in the future. Faulty judgments, simple errors or mistakes, or the failure of our personnel to adhere to established controls and procedures may make it difficult for us to ensure that the objectives of the control system are met. A failure of our controls and procedures to detect other than inconsequential errors or fraud could seriously harm our business and results of operations.

Our limited senior management team size may hamper our ability to effectively manage a publicly traded company while developing our products and harm our business.

Our management team has experience in the management of publicly traded companies and complying with federal securities laws, including compliance with recently adopted disclosure requirements on a timely basis. They realize it will take significant resources to meet these requirements while simultaneously working on licensing, developing and protecting our IP. Our management will be required to design and implement appropriate programs and policies in responding to increased legal, regulatory compliance and reporting requirements, and any failure to do so could lead to the imposition of fines and penalties and harm our business.

Our Chief Executive Officer does not devote her full-time efforts to us.

While we believe that Jamie Sulley's services will be available to us, she currently has a non-exclusive contractual agreement to perform the services of Chief Executive Officer for other companies. To assist with the ongoing operation of our company, we have contracted with other service providers to assist our Chief Executive Officer. To supplement this arrangement, we occupy office space adjacent to Ms. Sulley's current place of business in order to facilitate a proximal work environment for her. There can be no assurances that the financial arrangements that we have made for Ms. Sulley, or the provisions of the management consulting agreement we entered into will be effective and adequate at this stage in our development to retain her services.

The limited trading market for our common stock results in limited liquidity for shares of our common stock and significant volatility in our stock price.

Although prices for our shares of common stock are quoted on the OTC electronic interdealer quotation system ("OTCQB"), there is little current trading and no assurance can be given that an active public trading market will develop or, if developed, that it will be sustained. The OTCQB is generally regarded as a less efficient and less prestigious trading market than other national markets. There is no assurance if or when our common stock will be quoted on another more prestigious exchange or market. Active trading markets generally result in lower price volatility and more efficient execution of buy and sell orders. The absence of an active trading market reduces the liquidity of our common stock.

The market price of our stock is likely to be highly volatile because for some time there will likely be a thin trading market for the stock, which causes trades of small blocks of stock to have a significant impact on our stock price. As a result of the lack of trading activity, the quoted price for our common stock on the OTCQB is not necessarily a reliable indicator of its fair market value. Further, if we cease to be quoted, holders of our common stock would find it more difficult to dispose of, or to obtain accurate quotations as to the market value of, our common stock, and the market value of our common stock would likely decline.

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Trading in our common stock will be subject to regulatory restrictions since our common stock is considered a "penny stock."

Our common stock is currently, and in the near future will likely continue to be, considered a "penny stock." The SEC has rules that regulate broker-dealer practices in connection with transactions in "penny stocks." Penny stocks generally are equity securities with a price of less than \$5.00 (other than securities registered on certain national securities exchanges or quoted on the NASDAQ system, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system). The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document prepared by the SEC, which specifies information about penny stocks and the nature and significance of risks of the penny stock market. The broker-dealer also must provide the customer with bid and offer quotations for the penny stock, the compensation of the broker-dealer and any salesperson in the transaction, and monthly account statements indicating the market value of each penny stock held in the customer's account. In addition, the penny stock rules require that, prior to a transaction in a penny stock not otherwise exempt from those rules; the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. These disclosure and other requirements may adversely affect the trading activity in the secondary market for our common stock.

Substantial future sales of our common stock in the public market could cause our stock price to fall.

Sales of a significant number of shares of our common stock in the open market could cause additional harm to the market price of our common stock. Further reduction in the market price for our shares could make it more difficult to raise funds through future equity offerings.

Some of our shares may also be offered from time-to-time in the open market pursuant to Rule 144, and these sales may have a depressive effect on the market for our shares. In general, a non-affiliate who has held restricted shares for a period of six months may sell an unrestricted number of shares of our common stock into the market.

We have not paid dividends in the past and do not expect to pay dividends for the foreseeable future, and any return on investment may be limited to potential future appreciation on the value of our common stock.

We currently intend to retain future earnings to support the development and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Our payment of future dividends will be at the discretion of our Board of Directors after taking into account various factors, including without limitation, our financial condition,

operating results, cash needs, growth plans and the terms of any credit agreements that we may be a party to at the time. To the extent we do not pay dividends, our stock may be less valuable because a return on investment will only occur if and to the extent our stock price appreciates, which may never occur. In addition, investors must rely on sales of their common stock after price appreciation as the only way to realize their investment, and if the price of our stock does not appreciate, then there will be no return on investment. Investors seeking cash dividends should not purchase our common stock.

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Our officers, directors and principal stockholders can exert significant influence over us and may make decisions that are not in the best interests of all stockholders.

As of April 25, 2013 our officers, directors and principal stockholders (greater than 5% stockholders) collectively own approximately 24.66% of our outstanding common stock, and approximately 48.74% of our fully-diluted common stock. As a result of such ownership, these stockholders will be able to affect the outcome of, or exert significant influence over, all matters requiring stockholder approval, including the election and removal of directors and any change in control. In particular, this concentration of ownership of our common stock could have the effect of delaying or preventing a change of control of us or otherwise discouraging or preventing a potential acquirer from attempting to obtain control of us. This, in turn, could have a negative effect on the market price of our common stock. It could also prevent our stockholders from realizing a premium over the market prices for their shares of common stock. Moreover, the interests of this concentration of ownership may not always coincide with our interests or the interests of other stockholders, and accordingly, they could cause us to enter into transactions or agreements that we would not otherwise consider.

Anti-takeover provisions may limit the ability of another party to acquire us, which could cause our stock price to decline.

Our certificate of incorporation, as amended, our bylaws and Delaware law contain provisions that could discourage, delay or prevent a third party from acquiring us, even if doing so may be beneficial to our stockholders. In addition, these provisions could limit the price investors would be willing to pay in the future for shares of our common stock.

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#### Item 2. PROPERTIES.

On September 28, 2010, we entered into an office lease agreement effective as of October 1, 2010, with Princeton Corporate Plaza, LLC for \$3,794 per month including expenses. We leased 2,046 square feet of office and laboratory space in the building located at 11 Deer Park Drive, Suite 204, in the township of South Brunswick in the County of Middlesex, State of New Jersey. The lease term began on October 1, 2010, and ended on September 30, 2011. The lease agreement provided that the lease continue on a month to month basis after expiration of the stated term, and can be terminated by either party upon 30 days advance notice. In February 2013, we moved our offices to 5825 Oberlin Drive, San Diego, California. We lease office space for \$3,500 per month which includes parking and service fee.

### Item 3. LEGAL PROCEEDINGS.

On October 1, 2010, Robert Love, a former Chief Financial Officer of the Company, filed an amended complaint in *Love v. Alfacell Corp. et al.*, Case No. 3:09-cv-05199-MLC-LHG (the "Amended Complaint"), against the Company and certain of its current and former directors in the U.S. District Court, District of New Jersey, asserting violations of federal and state securities laws, direct and derivative common law claims for fraud and breach of fiduciary duty, a direct claim for negligent misrepresentation and derivative claims for gross negligence and corporate waste in connection with the Company's Phase IIIb clinical trial for ONCONASE. On March 8, 2012, the Company settled for \$50,000.

Premier Research Group filed and served a lawsuit against the Company in the Superior Court of New Jersey, Law Division, Essex County, on or about July 26, 2009, seeking the recovery of professional fees that arose from clinical trials purportedly performed in Europe by Premier Research Group as assignee of a contract between Tamir Biotechnology, Inc. and IMFORM GmbH dated October 27, 2005. In August 2010, both parties entered into a Stipulation of Settlement Agreement ("Stipulation") whereby the Company was to make a payment to Premier of \$100,000 which was to be accepted as a payment in full if paid in accordance with the terms of the Stipulation. Pursuant to the terms of the settlement, the Company made four equal installment payments in the aggregate amount of \$100,000 in full and final settlement of this matter. The final installment was made in February 2011.

I & G Garden State, LLC ("I&G") filed and served a complaint against the Company in the Superior Court of New Jersey Law Division, Special Civil Part Landlord-Tenant Section, Somerset County, on or about October 30, 2009, for non-payment of rent and failure to maintain security deposit. The complaint sought to have the Company vacate the property. On November 13, 2009, the Company and I&G mutually agreed that the Company would vacate the property on or before December 31, 2009. In January 2010, the Company vacated the facility as per mutual agreement. In February 2010, I&G withdrew the remaining balance of the Company's secured irrevocable letter of credit which was placed in March 2007 of \$81,000. On February 5, 2010, I&G commenced an action against the Company. The lawsuit seeks unspecified damages for an alleged breach of a lease agreement dated March 14, 2007 between the Company and I & G. On or before November 1, 2010, the Company and I&G entered into a Settlement Agreement and Mutual Release whereas I&G agreed to receive \$200,000 in consideration of the release in full and complete settlement of all claims made by I&G. In November 2010 and February 2011, the Company paid the

settlement amount of \$200,000 in accordance with the terms of the settlement agreement.

On February 23, 2012, the Company settled an action with Pharmatech Oncology, Inc. ("Pharmatech") whereby the Company agreed to use Pharmatech if the Company conducts any oncology clinical trial using ONCONASE®. Additionally, the Company agreed to pay Pharmatech \$200,000 in consideration of entering into the settlement.

On May 15, 2012, Charles Muniz, the Company's former President, Chief Executive Officer and Chief Financial Officer and a former director of the Company, filed a complaint against the Company asserting that he had been wrongfully discharged by the Company in violation of federal and state laws. More specifically, the complaint alleged the Company terminated Mr. Muniz's employment and position as an executive officer of the Company in retaliation of Mr. Muniz's complaints regarding the Company's failure to disclose material information in reports filed with the SEC. The complaint seeks unspecified compensatory and punitive damages. The Company believes that the claims are meritless and intends to defend the case vigorously.

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On July 26, 2012, certain investors and stockholders of the Company who own more than 7,500,000 shares of the Company's common stock filed a complaint against the Company and certain current and former executive officers and directors of the Company alleging fraud and breaches of fiduciary duty. The complaint asserts that the Company and the other defendants failed to properly pursue the Company's application with the FDA for approval of its therapeutics. The complaint alleges that the Company and the other defendants committed securities fraud by failing to disclose material information in reports filed with the SEC in violation of federal and state securities laws. The complaint also alleges that the executive offices and directors of the Company breached their fiduciary duties to the Company's stockholders by failing to take corrective action and by failing to accurately disclose material information to the Company's stockholders. In addition to direct claims made by the plaintiffs, the complaint asserts derivative claims for fraud and breaches of fiduciary obligations on behalf of all stockholders of the Company. The complaint seeks over \$7,000,000 in compensatory damages and an unspecified amount in punitive damages. The Company believes the claims are baseless and intends to defend the case vigorously.

The SEC has commenced an administrative proceeding against the Company alleging that the Company is delinquent in filing its periodic filings with the SEC since the Company has not filed any of its periodic reports since the quarterly report on Form 10-Q filed for the period ended January 31, 2011. The purpose of the hearing is to determine whether it is appropriate for the SEC to suspend for a period of up to 12 months or to permanently revoke the registration of the Company's common stock pursuant to Section 12 of the Securities Exchange Act of 1934. This action was instituted concurrently with a temporary suspension of trading of the common stock ordered by the SEC from January 25, 2013 through February 7, 2013.

Item 4. RESERVED.

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#### Part II

# Item 5. <u>MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS</u> AND ISSUER PURCHASES OF EQUITY SECURITIES.

Currently, our stock is quoted on OTC Markets under the designation Caveat Emptor. OTC Markets identifies securities with a Caveat Emptor symbol to inform investors that, in OTC Markets' opinion, there is reason to exercise additional care and perform thorough due diligence in making investment decisions for a particular security. Our common stock has been quoted on the OTC Markets since our delisting from the Nasdaq Capital Market, or Nasdaq, on January 6, 2009 for failure to comply with the \$35 million minimum market value requirement under Marketplace Rule 4310(c)(3)(B) or the \$1 per share minimum bid price requirement under Marketplace Rule 4310(c)(4). In addition, we also did not meet the \$2.5 million minimum stockholders' equity requirement under Marketplace Rule 4310(c)(3)(A) or the requirement for a minimum net income from continuing operations of \$500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years under Marketplace Rule 4310(c)(3)(C). Our common stock remains thinly traded at times and you may be unable to sell our common stock during times when the trading market is limited.

Prior to January 6, 2009, our common stock was listed on Nasdaq and had traded under the symbol "ACEL" since September 9, 2004. Before September 9, 2004, our common stock was traded on the OTC Bulletin Board (OTCBB).

As of April 25, 2013, there were approximately 968 stockholders of record of our common stock.

The SEC has commenced an administrative proceeding against the Company alleging the Company is delinquent in filing its periodic filings with the SEC since the Company has not filed any of its periodic reports since the quarterly report on Form 10-Q filed for the period ended January 31, 2011. The purpose of the hearing is to determine whether it is appropriate for the SEC to suspend for a period of up to 12 months or to permanently revoke the registration of the Company's common stock pursuant to Section 12 of the Securities Exchange Act of 1934. This action was instituted concurrently with a temporary suspension of trading of the common stock ordered by the SEC from January 25, 2013 through February 7, 2013.

The Company intends to defend itself in the SEC administrative action and to file its delinquent periodic filings with the SEC. The Company's Board of Directors believes the retention of a new management team are significant steps toward ensuring that the Company will be in a position to comply with its future and past reporting obligations.

The following table sets forth the range of high and low sale prices of our common stock for the fiscal years ended July 31, 2011 and 2010. The prices were obtained from Yahoo Finance, and are believed to be representative of inter-dealer prices, without retail mark-up, mark-down or commission, and may not necessarily represent actual transactions.

	High	Low
Year Ended July 31, 2011:		
First Quarter	\$0.52	\$0.18
Second Quarter	0.49	0.25
Third Quarter	0.33	0.13
Fourth Quarter	0.20	0.08
Year Ended July 31, 2010:		
First Quarter	\$0.35	\$0.18
Second Quarter	0.30	0.14
Third Quarter	0.35	0.11
Fourth Quarter	0.30	0.13

#### **Dividends**

We have not paid dividends on our common stock since inception, and we do not plan to pay dividends in the foreseeable future. Any earnings we may realize will be retained to finance our growth. Additionally, pursuant to the terms of the Senior Secured Notes issued in connection with our October 2009 private financing, we are not permitted to declare or pay any cash dividends or distributions on its outstanding capital stock for so long as the Senior Secured Notes are outstanding.

# **Equity Compensation Plan Information**

The information called for by Item 5(a) relating to compensation plan information is incorporated herein by reference to Item 12—Security Ownership of Certain Beneficial Owners and Management and Related Stock Matters of this annual report on Form 10-K.

## **Recent Sales of Unregistered Securities**

In April 2011 the Company completed the sale of 2,500,000 shares of its common stock and the issuance of warrants to purchase 2,500,000 common shares pursuant to an agreement with Unilab LP. The company received proceeds of \$500,000. The warrants have a 5-year term and a purchase price of \$0.50 per share.

On December 14, 2012, Company completed a private placement of 10 "Units" at a price of \$100,000 per Unit, for aggregate gross consideration of \$1 million (the "Offering"), pursuant to a Securities Purchase Agreement (the "Purchase Agreement") dated as of December 11, 2012. Each Unit consisted of (i) 13,846,945 shares of the Company's common stock, par value \$.001 per share ("Common Stock"), (ii) 1,000 shares of Series A Convertible Preferred Stock of the Company (the "Preferred Shares"), each such Preferred Share being initially convertible into 17,718.52 shares of Common Stock, and (iii) ten-year Common Stock Purchase Warrants (the "Warrants"), to purchase 12,626,184 shares of Common Stock at an exercise price of \$0.003168 per share.

The lead investor in the Offering was Europa International Inc. ("Europa"), a beneficial owner of more than five percent of the Company's voting securities prior to the Offering, which purchased 5.25 Units.

Upon completion of the Offering, there were issued and outstanding approximately 577,000,000 shares of Common Stock on a fully-diluted basis, of which 315,654,607 (or 70%) were issued in the Offering. The Company's Certificate of Incorporation only authorizes the issuance of 250,000,000 shares of Common Stock. The Preferred Shares issued in the Offering, which are convertible into an aggregate of 177,185,153 shares of Common Stock, will automatically convert into shares of the Common Stock on the date the Company files an amendment to its Certificate of Incorporation increasing the authorized number of shares of Common Stock and/or effecting a reverse stock split so that the Company has a sufficient number of authorized and unissued shares of Common Stock so as to permit the conversion of all outstanding Preferred Shares and all other convertible securities of the Company. A copy of the Certificate of Designations, Powers, Preferences and Rights of the Preferred Shares (the "the Certificate of Designations") has been filed as Exhibit 3.1 to this Report and is incorporated herein by reference.

In connection with the Offering, and as a condition precedent thereto under the Purchase Agreement, the holders of a majority in principal amount (the "Requisite Holders") of the Company's outstanding 5% Senior Secured Convertible Promissory Notes (the "Notes"), entered into a Consent and Waiver (the "Consent") under which (i) the Notes were amended to provide for the automatic conversion of the outstanding principal and interest of all of the Notes upon the election of the Requisite Holders, (ii) the Requisite Holders elected to convert all outstanding principal and interest under the Notes, of \$3,891,838, into shares of Common Stock at \$0.15 per share (the conversion price under the Notes), and (iii) the exercise price of the Series B Warrants held by the holders of the Notes were reduced from \$0.25 per share to \$0.01 per share.

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In connection with the Offering, the Company also entered into a Third Amendment to Investor Rights Agreement (the "Investor Rights Agreement Amendment") with the purchasers of the Units and the Requisite Holders under which the Company has provided registration rights with respect to the Common Stock issued in the Offering and the shares of Common Stock issuable upon conversion of the Preferred Shares and exercise of the Warrants.

In connection with the above transactions, we did not pay any underwriting discounts or commissions. None of the sales of securities described or referred to above was registered under the Securities Act of 1933, as amended (the "Securities Act"). Each of the purchasers was an accredited investor with whom we or one of our affiliates had a prior business relationship, and no general solicitation or advertising was used in connection with the sales. In making the sales without registration under the Securities Act, we relied upon the exemption from registration contained in Section 4(2) of the Securities Act.

### ITEM 6. SELECTED FINANCIAL DATA.

Not Applicable

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# Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

This discussion summarizes the significant factors affecting our consolidated operating results, consolidated financial condition, liquidity and cash flows for the years ended July 31, 2011 and 2010. The discussion and analysis that follows should be read together with the consolidated financial statements and the notes to the consolidated financial statements included elsewhere in this report. Management's Discussion and Analysis of Financial Condition and Results Of Operations is provided as a supplement to the accompanying consolidated financial statements and footnotes to help provide an understanding of our financial condition, the changes in our financial condition and our results of operations. Except for historical information, the matters discussed in this Management's Discussion and Analysis of Consolidated Financial Condition and Results of Consolidated Operations are forward looking statements that involve risks and uncertainties and are based upon judgments concerning various factors that are beyond our control. Our actual results could differ materially from the results anticipated in any forward-looking statements as a result of a variety of factors, including those discussed in Section 1A above – "Risk Factors."

#### Overview

We are a biopharmaceutical company primarily engaged in the discovery and development of a new class of antiviral therapeutic drugs for the treatment of pathological conditions. Our proprietary drug discovery and development program consists of novel therapeutics which are being developed from amphibian ribonucleases (RNases).

Since our inception in 1981, we have devoted the vast majority of our resources to the research and development of ONCONASE®, as well as other related drug candidates. In recent years we have focused our resources towards the completion of the clinical program for ONCONASE® in patients suffering from unresectable malignant mesothelioma ("UMM").

On February 4, 2011, we decided to suspend the Phase II trial of ONCONASE® in combination with carboplatinum regimens in patients suffering from non-small cell lung cancer who have reached maximum progression after receiving two cycles of Alimta plus Carboplatin. Given our limited resources and based upon previously reported positive *in vitro* results, we shifted our focus to the completion of *in vivo* studies for Cytomegalovirus ("CMV") and human papillomavirus ("HPV").

We have incurred losses since inception and we have not received the Food and Drug Administration ("FDA") approval of any of our drug candidates. We expect to continue to incur losses for the foreseeable future as we continue our efforts to receive marketing approval for our drug candidates, which includes the sponsorship of human clinical trials. Until we are able to consistently generate revenue through the sale of drug or non-drug products, we anticipate we will be required to fund the development of our pre-clinical compounds and drug product candidates primarily by other means, including, but not limited to, licensing the development or marketing rights to some of our drug candidates to

third parties, collaborating with third parties to develop our drug candidates, or selling Company issued securities.

# **Results of Operations**

Fiscal Year Ended July 31, 2011, as compared to Fiscal Year Ended July 31, 2010

Revenue for fiscal 2011 was \$5.2 million compared to \$0 for fiscal 2010, an increase of \$5.2 million. The increase was due to a nonrefundable license fee recognized in fiscal 2011.

Research and development expense for fiscal 2011 was \$0.8 million compared to \$0.5 million for fiscal 2010, an increase of \$0.4 million, or 60%. The increase was primarily related to a settlement of professional fees related to a small lung cancer phase II clinical trial.

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General and administrative expenses for fiscal 2011 was \$(0.2) million compared to \$1.7 million for fiscal 2010, a decrease of \$1.9 million. This decrease was primarily due to the reversal of \$1,228,572 in compensation expense related to 1,000,000 stock options, tied to performance, issued in April 2008 to the Company's Founder. During fiscal 2011, the Company concluded that the performance condition was deemed improbable; therefore, the expense to-date was reversed in accordance to FASB ASC 718, "Compensation – Stock Compensation." In addition, the decrease in expenses was due to lower legal fees and other costs associated with being public, as the Company did not file all quarterly and the year-end annual report, as well as compensation expense and other general office expenses, decreased due to our reduced operations.

Interest income and other income for the fiscal 2011 increased by \$9.6 million compared to fiscal 2010. For fiscal 2010, the Company reported expenses of \$12.6 million. This increase was directly due to change in the market-to-market valuation of the derivative liability of the convertible debenture and warrants we issued in October 2009.

New Jersey has legislation permitting certain corporations in New Jersey to sell a portion of their state tax loss carry forwards and state research and development credits to obtain tax benefits. For the state fiscal 2010 (July 1, 2009 to June 30, 2010), we had \$723,000 of total available state tax benefit that was saleable. In February 2010, we received \$647,000 from the sale of our total available state tax benefit, which was recognized as state tax benefit in fiscal 2010. In fiscal 2011, the Company did not qualify for state tax benefits.

The net profit for fiscal 2011 was \$14.1 million compared to a net loss of \$14.2 million in fiscal 2010. This net profit is primarily due to recognizing revenue of \$5.2 million, \$10.5 million decrease in the fair value of the warrant liability and a reversal of \$1.4 million compensation expenses, which are a non cash income and reduced operating expenses. The market-to-market valuation of our warrants resulted in the recording of an \$11.6 million expense for fiscal 2010.

### Liquidity and Capital Resources

The net losses from the date of inception, August 24, 1981 to July 31, 2010, were \$109 million. It is anticipated that losses will continue over the coming years. We expect to use cash and equivalents to fund our operating activities. Future liquidity and capital requirements will depend on numerous factors, including the progress of research and product development programs, obtaining approvals and complying with regulations; the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and the effect of competing technological and market developments.

At July 31, 2011, cash and equivalents totaled \$0.3 million, as compared to \$1.5 million at July 31, 2010 (including restricted cash). During fiscal 2011, we used \$0.5 million of cash in our operating activities. This amount compares to \$2.8 million used in our operating activities during fiscal 2010. The decrease of \$2.3 million is primarily due to our reduced clinical and pre-clinical research and development efforts for ONCONASE<sup>â</sup>.

In connection with our private financing completed in October 2009, we also entered into an escrow agreement whereby certain investors placed \$1,600,000 of the proceeds paid for their Units in an escrow account pursuant to the terms of the Securities Purchase Agreement. Such amounts were disbursed from the escrow account to satisfy obligations we owed to clinical research organizations, hospitals, doctors and other vendors and service providers associated with the clinical trials for our ONCONASE<sup>â</sup> product. The escrow agreement was terminated on April 20, 2011 as all funds had been used.

In April 2011, the Company completed the sale of 2,500,000 shares of its common stock and the issuance of warrants to purchase 2,500,000 common shares pursuant to an agreement with Unilab LP. The Company received proceeds of \$500,000. The warrants have a 5-year term and a purchase price of \$0.50 per share.

On December 14, 2012, the Company completed a private placement of 10 "Units" at a price of \$100,000 per Unit, for aggregate gross consideration of \$1 million pursuant to the Purchase Agreement. Each Unit consisted of (i) 13,846,945 shares of Common Stock, (ii) 1,000 Preferred Shares, each such Preferred Share being initially convertible into 17,718.52 shares of Common Stock, and (iii) Warrants to purchase 12,626,184 shares of Common Stock at an exercise price of \$0.003168 per share.

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In connection with the Offering, and as a condition precedent thereto under the Purchase Agreement, the Requisite Holders of the Company's outstanding Notes, entered into a Consent and Waiver under which (i) the Notes were amended to provide for the automatic conversion of the outstanding principal and interest of all of the Notes upon the election of the Requisite Holders, (ii) the Requisite Holders elected to convert all outstanding principal and interest under the Notes, in the aggregate amount of \$3,891,838, into shares of Common Stock at a price \$0.15 per share (the conversion price under the Notes), and (iii) the exercise price of the Series B Warrants held by the holders of the Notes were reduced from \$0.25 per share to \$0.01 per share.

The Company has financed its operations since inception primarily through the sale of our equity securities and convertible debentures in registered offerings and private placements. Additionally, we have raised capital through other debt financings, the sale of our state tax benefit and research products. Because our business does not generate positive cash flow from operating activities, the Company will need to raise additional capital in order to fully commercialize our product or to fund development efforts relating to additional indications. To the extent additional capital is not available when needed, the Company may be forced to abandon some or all of its development and commercialization efforts, which would have a material adverse effect on the prospects of the business. Based upon the reduced operations, we currently believe that our cash reserves can support our activities through September 2013. We may seek to satisfy future funding requirements through public or private offerings of securities or with collaborative or other arrangements with corporate partners. Additional financing or strategic transactions may not be available when needed or on terms acceptable to us, if at all. If adequate financing is not available, we may be required to delay, scale back, or eliminate certain of our research and development programs, relinquish rights to certain of our technologies, drugs or products, or license third parties to commercialize products or technologies that we would otherwise seek to develop ourselves.

### **Off-Balance Sheet Arrangements**

We have no debt, no exposure to off-balance sheet arrangements, no special purpose entities, nor activities that include non-exchange-traded contracts accounted for at fair value as of July 31, 2011.

# Critical Accounting Policies

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The notes to the financial statements included in Item 8 contain a summary of the significant accounting policies and methods used. The preparation of financial statements in conformity with U.S. generally accepted accounting principles or GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expense during the reporting period. Actual results

could differ from those estimates.

We recognize revenue in accordance with Staff Accounting Bulletin ("SAB") No. 104, "Revenue Recognition," issued by the staff of the SEC. Under SAB No. 104, revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred and/or services have been rendered, the sales price is fixed or determinable, and collectability is reasonably assured. We enter into marketing and distribution agreements, which contain multiple deliverables. We evaluate whether these deliverables constitute separate units of accounting to which total arrangement consideration is allocated.

The Company adopted the provisions of FASB ASC 718, which establishes accounting for equity instruments exchanged for employee services. Under the provisions of FASB ASC 718, share-based compensation is measured at the grant date, based upon the fair value of the award, and is recognized as an expense over the option holders' requisite service period (generally the vesting period of the equity grant). The Company expenses its share-based compensation under the ratable method, which treats each vesting tranche as if it were an individual grant.

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The Company adopted the provisions of FASB ASC 505-50, which establishes accounting for equity-based payments to non-employees. Measurement of compensation cost related to common shares issued to non-employees for services is based on the value of the services provided or the fair value of the shares issued. Each transaction is reviewed to determine the more reliably measurable basis for the valuation. The measurement of non-employee stock-based compensation is subject to periodic adjustment as the underlying equity instrument vests.

The Company adopted the provisions of FASB ASC 820, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

FASB ASC 820 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, FASB ASC 820 establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity's own assumptions about market participant assumptions (unobservable inputs classified within Level 3 of the hierarchy).

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access. Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals. Level 3 inputs are unobservable inputs for the asset or liability which are typically based on an entity's own assumptions, as there is little, if any, related market activity. In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability.

## Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable

#### Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

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The response to this Item is submitted as a separate section of this report commencing on Page F-1.

# Item 9. <u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.</u>

None.

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### Item 9A. CONTROLS AND PROCEDURES.

#### **Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934, as amended is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer, who serves as our principal executive officer and our Chief Financial officer, who serves as our principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosure as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act.

As of July 31, 2011, our Chief Executive Officer and Chief Financial Officer conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of July 31, 2011, our disclosure controls and procedures were not effective.

### Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting ("ICFR") as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act and for assessing the effectiveness of internal control over financial reporting.

Because of its inherent limitations, ICFR may not prevent or detect misstatements. In addition, projections of any evaluation of effectiveness of ICFR to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management has assessed the effectiveness of our ICFR as of July 31, 2011. In making its assessment of ICFR, management used the criteria established in Internal Control — Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission. This assessment included an evaluation of the design of our ICFR and testing of the operational effectiveness of those controls. Based on the results of this assessment, management has concluded that our ICFR was not effective as of July 31, 2011 due to the limited size of our staff and budget.

# **Changes in Internal Control over Financial Reporting**

There were no changes in our ICFR that occurred during the fourth quarter of the year ended July 31, 2011 that have materially affected, or that are reasonably likely to materially affect, our ICFR.

# Item 9B. OTHER INFORMATION.

None.

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#### **PART III**

# ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The following table sets forth the names, ages and positions of our current executive officers and directors. All directors serve until the next annual meeting of stockholders or until their successors are elected and qualified. Officers are appointed by our Board of Directors ("Board") and their terms of office are, except to the extent governed by an employment contract, at the discretion of our Board of Directors.

### **Board of Directors**

Name	Age	e Director Since	Current Position With Company
Jamie Sulley	47	2013	President and Director
John P. Brancaccio	65	2004	Director
Fred Knoll	58	2013	Director
Francis Patrick Ostronic	57	2013	Director
David Sidransky, M.D.	53	2004	Chairman of the Board
Paul M. Weiss, Ph.D.	55	2003	Director

#### **Executive Officers**

# Name Age Officer Since Current Position With Company

Jamie Sulley 47 2013 President, Chief Executive Officer, and Director Joanne M. Barsa 51 2013 Chief Financial Officer and Secretary

Officers of Tamir hold office until their successors are elected and qualified or until their earlier removal, death or resignation.

Business Experience of Directors and Executive Officers

The Company's Directors and Executive Officers have provided the following information about their principal occupation, business experience and other matters.

*Jamie Sulley*, joined us on February 5, 2013 as our President and member of our Board of Directors. Ms. Sulley has over 25 years' experience working with a variety of biotechnology and medical device companies in various stages of

development. Ms. Sulley is currently the Chief Operating Officer of Tensys Medical, Inc. and prior to Tensys, she was the General Manager for Pharmalink Consulting, Inc., where she was responsible for growing Pharmalink to eight offices on three continents supporting diverse clients across all major healthcare sectors. Ms. Sulley holds a PhD/MPH from the University of Liverpool School of Medicine.

Joanne M. Barsa, joined us on February 5, 2013 as our Chief Financial Officer. Ms. Barsa has been the Chief Executive Officer of Barsa & Company since 1987, a financial and accounting services consulting firm. Ms. Barsa holds a B.S. in Accounting from San Diego State University and is a member of the American Institute of Certified Public Accountants and the California Society of CPAs. Ms. Barsa is also a member of the Ernst & Young Alumni Association, Vistage International, Provisors Carmel Valley and San Diego Business Resources. Ms. Barsa filed Chapter 7 bankruptcy in May 2009. The bankruptcy was discharged in September 2009.

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*John P. Brancaccio*, has served as a director of our company since April 2004. Mr. Brancaccio has been the Chief Financial Officer of Accelerated Technologies, Inc., an incubator for medical device companies since 2004. From May 2002 until March 2004, Mr. Brancaccio was the Chief Financial Officer of Memory Pharmaceuticals Corp., a biotechnology company. From 2000 to 2002, he was the Chief Financial Officer/Chief Operating Officer of Eline Group, an entertainment and media company. Mr. Brancaccio is currently a director of Synergy Pharmaceutical, Inc. as well as a director of Trovagene, Inc. He is a retired CPA and a graduate of Seton Hall University. Mr. Brancaccio's chief financial officer experience provides him with valuable financial and accounting expertise which the Board believes qualifies him to serve as an independent director of our company.

Fred Knoll, joined the Board on February 5, 2013. Since 1987, Mr. Knoll has been the principal and portfolio manager at Knoll Capital Management, an investment company managing funds over the last two decades in areas such as emerging growth companies, restructurings and China. During the 80's and early 90's, he was Chairman of the Board of Directors of Telos Corporation, a computer systems integration company, served as investment manager for General American Investors, was the United States representative on investments in leveraged buyouts and venture capital for Murray Johnstone, Ltd. of Glasgow, UK, and headed the New York investment group of Robert Fleming, Inc., at the time, a leading United Kingdom merchant bank subsequently acquired by JP Morgan, managing a venture capital fund and the U.S. research team. Mr. Knoll started his investment career as an investment analyst at Capital Research ("Capital Group") in the early 80s and held positions in sales and marketing with Wang Inc. and Data General and software engineering with Computer sciences Corporation in the late 70s. Mr. Knoll is a Director of Tamir Biotechnology, Inc. and AtheroNova. Mr. Knoll holds a Bachelor's of Science in Electrical Engineering and Computer Science from Massachusetts Institute of Technology ("M.I.T."), a Bachelor's of Science in Management from the Sloan School at M.I.T., and an M.B.A. from Columbia University in Finance and was a member of the Columbia University International Fellows Program.

Francis Patrick Ostronic, joined the Board on February 5, 2013. Mr. Ostronic received his Bachelors of Arts in Economics & Accounting from the College of the Holy Cross (Worcester, MA). Additionally, Mr. Ostronic received his Masters of Science in Accounting from Old Dominion University (Norfolk, VA) and his Juris Doctorate from the University of Maryland. Mr. Ostronic worked as a CPA for various firms and on his own in the Baltimore-Washington area after serving on active duty with the Navy (NROTC in college). Since November 2006, Mr. Ostronic has worked full-time for US Pharmacia International, Inc. (USPI) as a corporate officer, primarily as a Group Chief Financial Officer.

David Sidransky, M.D., joined the Board in May 2004, was elected Chairman of the Board in January 2008 and is the Chairman of our Scientific Advisory Board. Dr. Sidransky is a founder of several private biotechnology companies and has served on scientific advisory boards of numerous private and public companies, including Medimmune, Telik, Roche and Amgen. He is now chairman of the board of Champions Oncology Inc and on the board of Rosetta Genomics, Immune pharmaceuticals, and Celsus. Currently, Dr. Sidransky is the Director of the Head and Neck Cancer Research Division at Johns Hopkins University School of Medicine. In addition, he is Professor of Oncology, Otolaryngology-Head and Neck Surgery, Cellular & Molecular Medicine, Urology, Genetics, and Pathology at John Hopkins University and Hospital. Dr. Sidransky is certified in Internal Medicine and Medical Oncology by the

American Board of Medicine. Dr. Sidransky received his B.A. from Brandeis University and his M.D. from the Baylor College of Medicine. Because of his strong background of service on the boards of various biopharmaceutical and life sciences companies and his involvement in capital raising and strategic transactions in our industry, we believe that Dr. Sidransky provides a unique perspective and useful insight to our board.

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*Paul Weiss, Ph.D.*, joined the Board in February 2003. Since October 2007, Dr. Weiss has been a Managing Director at Venture Investors, LLC, a Madison, Wisconsin-based venture capital group focusing on early-stage life sciences companies. Prior to joining Venture Investors, LLC, Dr. Weiss was President of the Gala Biotech business unit of Cardinal Health (now Catalent Pharma Solutions) from February 2002 until October 2007. Prior to joining Gala, from 1998 to 2001, Dr. Weiss was Vice President of Technology and Product Licensing at 3-Dimensional Pharmaceuticals (3DP) and Dr. Weiss was Director of Licensing for Wyeth Pharmaceuticals. Dr. Weiss holds a Ph.D. in Biochemistry and an MBA from the University of Wisconsin-Madison and a B.Sc. in Biochemistry from the Carleton University Institute of Biochemistry in Ottawa, Ontario. Because of his strong background of service on the boards of various biopharmaceutical and life sciences companies and his involvement in capital raising and strategic transactions in our industry, we believe that Dr. Weiss provides a unique perspective and useful insight to our board.

Significant Employees
None.
Family Relationships
There are no family relationships among any of the Company's directors or executive officers.
Voting Arrangements
None.
Independent Directors
The Board determined the following directors are "independent" under Nasdaq Marketplace Rule 4200(a)(15): John P. Brancaccio, David Sidransky, M.D. Francis Patrick Ostronic and Paul M. Weiss, Ph.D. The Board has also

determined that the following directors (who are members of the Audit Committee) are "independent" in accordance with Section 10A(m)(3) of the Exchange Act: John P. Brancaccio, David Sidransky, M.D. and Paul M. Weiss, Ph.D.

### **Board Committee Membership**

The Board has standing Compensation, Corporate Governance and Nominating, Audit, Research and Clinical Oversight, and Commercial and Business Development Oversight Committees. The current membership of the standing committees is set forth in the following table:

Name	Compensation Committee	Corporate Governance and Nominating Committee	Audit Committee	Research and Clinical Oversight Committee	Commercial and Business Development Oversight Committee
Jamie Sulley					
John P.	**	*	**		
Brancaccio					
Fred Knoll					
Patrick			*		
Ostronic					
David				**	
Sidransky,	*	**	*		*
M.D.					
Paul M. Weiss	S, <sub>*</sub>	*	*	*	**
Ph.D.					

<sup>\*</sup> Member

Compensation Committee. All of the members of Tamir's Compensation Committee are considered "independent directors" in accordance with Nasdaq Marketplace Rule 4200(a)(15). In fiscal 2011, the Compensation Committee did not meet.

On June 28, 2004, the Board adopted Tamir Biotechnology, Inc.'s Compensation Committee Charter. According to its charter, the Compensation Committee shall consist of at least three members, each of whom shall be non-employee directors who have been determined by the Board to meet the independence requirements of the Nasdag Stock Market.

The Compensation Committee Charter describes the primary functions of the Compensation Committee as follows:

<sup>\*\*</sup> Chair

Review and approve executive compensation on an annual basis, including the corporate goals and objectives to be used in evaluating the performance of the Chief Executive Officer and determining the Chief Executive Officer's compensation;

Review trends in management compensation, oversee the development of new compensation plans and, when necessary, approve the revision of existing plans;

Oversee management's decisions concerning compensation and performance for non-executive officers; Review the Company's incentive compensation and other share-based plans and recommend change to such plans to the Board as needed;

Administer stock plans and benefit programs and approve any amendments to existing plans; Recommend director compensation;

Evaluate compliance with the Company's compensation plans and policies; and Review the compensation policy for all of Tamir's employees.

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Corporate Governance and Nominating Committee. All of the members of Tamir's Corporate Governance and Nominating Committee are considered "independent directors" in accordance with Nasdaq Marketplace Rule 4200(a)(15). In fiscal 2011, the Corporate Governance and Nominating Committee did not meet.

The Corporate Governance and Nominating Committee was formed by the Board for the purpose of considering future nominees to the Board. On November 28, 2007, the Board adopted Tamir Biotechnology, Inc.'s Corporate Governance and Nominating Committee Charter. According to its charter, the Corporate Governance and Nominating Committee shall be comprised of at least three directors, each of whom shall meet the independence requirements of the Nasdaq Stock Market.

The Corporate Governance and Nominating Committee Charter describes the primary functions of the Corporate Governance and Nominating Committee as follows:

Identify and evaluate individuals qualified to serve as members of the Board (including individuals nominated by stockholders in proposals made in writing to the Company's Secretary that are timely received and that contain sufficient background information concerning the nominee to enable proper judgment to be made as to the nominee's qualifications);

Recommend for the Board's selection nominees for election as directors of the Company at the next annual or special meeting of stockholders at which directors are to be elected or to fill any vacancies then existing on the Board; Cause to be prepared and recommend to the Board the adoption of corporate governance guidelines and from time to time, review and assess the guidelines and recommend changes for approval by the Board;

From time to time, review and assess the Code of Business Conduct and Ethics and recommend changes for approval by the Board;

· Make recommendations to the Board regarding issues of management succession; and Conduct annual reviews and assessments of the adequacy of the Corporate Governance and Nominating Committee Charter and recommend any proposed changes to the Board for approval.

Audit Committee. All of the members of Tamir's Audit Committee are considered "independent directors" in accordance with Nasdaq Marketplace Rule 4200(a)(15) and Section 10A(m)(3) of the Securities Exchange Act. Tamir's Board has determined that Mr. Brancaccio qualifies as an "audit committee financial expert" as defined by Item 407 of Regulation S-K. In fiscal 2011, the Audit Committee met one time.

On November 25, 2008, the Board adopted the Amended and Restated Audit Committee Charter. According to its charter, the Audit Committee shall be comprised of at least three directors, each of whom shall meet the independence requirements of the Nasdaq Stock Market and Section 10A(m)(3) of the Exchange Act, and each of whom shall not have participated in the preparation of the financial statements of the Company at any time during the past three years. The Audit Committee's purpose, duties and responsibilities under its charter include those specified in the listing standards of the Nasdaq Stock Exchange for audit committees.

The Audit Committee Charter describes the primary functions of the Audit Committee as follows:

Appoint, evaluate and, as the Committee may deem appropriate, terminate and replace our independent registered public accounting firm;

Monitor the independence of our independent registered public accounting firm;

Determine the compensation to be paid to our independent registered public accounting firm;

Review with management and our independent registered public accounting firm the effect of regulatory and accounting initiatives as well as off-balance sheet structures on the Company's financial statements;

Review the experience and qualifications of the Company's senior finance executives as well as senior members of the independent registered public accounting firm team and the quality control procedures thereof;

Pre-approve all audit services and permitted non-audit services to be performed by our independent registered public accounting firm and establish policies and procedures for the engagement of our independent registered public accounting firm to provide permitted non-audit services;

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Conduct annual reviews and assessments of the adequacy of the Audit Committee Charter and the continued independence of the independent registered public accounting firm and recommend any proposed changes to the Board for approval;

Advise the Board with respect to the Company's policies and procedures regarding compliance with applicable laws and regulations and with the Company's Code of Business Conduct and Ethics;

Review all related-party transactions for potential conflict of interest situations and approve such related-party transactions;

Establish procedures for the confidential and anonymous receipt, retention and treatment of complaints regarding the Company's accounting, internal controls and auditing matters; and

Report to the Board on all of the foregoing matters.

Research and Clinical Oversight Committee. The Research and Clinical Oversight Committee ("Research Committee") was established in February 2007 and is chaired by David Sidransky, M.D. All of the members of Tamir's Research Committee are considered "independent directors" in accordance with Nasdaq Marketplace Rule 4200(a)(15).

The primary function of the Research Committee is to work closely with management and the Scientific Advisory Board to provide support and direction to the Company's research and development programs. The Research Committee functions as an advisory committee and does not hold formal committee meetings or take formal committee actions.

Commercial and Business Development Oversight Committee. The Commercial and Business Development Oversight Committee ("Development Committee") was established in February 2007 and is chaired by Paul Weiss, Ph.D. All of the members of Tamir's Development Committee are considered "independent directors" in accordance with Nasdaq Marketplace Rule 4200(a)(15).

The primary function of the Development Committee is to assist management in pursuing commercial and business development opportunities for the products currently in development. The Development Committee functions as an advisory committee and does not hold formal committee meetings or take formal committee actions.

Section 16(a) Beneficial Ownership Reporting Compliance

Based upon a review of filings with the SEC and written representations of certain reporting persons that no other reports were required, we believe that during fiscal 2011 all of our directors, executive officers and beneficial owners of more than 10% of any class of equity securities complied on a timely basis with the reporting requirements of Section 16(a) of the Exchange Act.

#### **Code of Ethics**

Tamir has adopted a written Code of Business Conduct and Ethics ("Code of Ethics") that applies to the Company's principal executive officer, principal financial officer, principal accounting officer, and controller and to all its other employees.

#### ITEM 11. EXECUTIVE COMPENSATION.

#### COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

During fiscal 2011, the members of the Board who served on the Compensation Committee were Messrs. John P. Brancaccio and Paul M. Weiss, Ph.D. As of the date of this annual report on Form 10-K, Mr. Brancaccio and Dr. Weiss are independent directors and have never been officers of Tamir. During fiscal 2011, no executive officer of Tamir served on the compensation committee or Board of Directors of any other entity which had any executive officer who also served on the Compensation Committee or Board of Tamir.

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#### COMPENSATION DISCUSSION AND ANALYSIS

#### **Compensation Philosophy**

Tamir's compensation program is based on the philosophy that the interests of our employees should be closely aligned with those of our stockholders. The Company's compensation program is based on the following principles:

Compensation opportunities should attract the best talent, motivate individuals to perform at their highest levels, reward outstanding achievement and retain the leadership and skills necessary for building long-term stockholder value:

Compensation should include a bonus potential which is tied directly to operating objectives; and Compensation should include a long-term incentive award generally in the form of stock option grants to increase ownership in the Company and encourage executives to manage from the perspective of owners of the Company.

The Compensation Committee believes that the compensation program for executive officers should reward the achievement of the short-term and long-term objectives of the Company, and that compensation should be related to the value created for its stockholders. However, given the highly volatile nature of biotechnology company stocks it would be impracticable for the Company to tie executive compensation solely to stock performance. In making its compensation decisions, the Compensation Committee generally reviews the progress made by the individual officer in attaining his or her individual performance goals and the progress made by the Company in its drug development programs, while keeping the Company's stock performance in mind. Generally, performance tied to the long-term objectives of the Company or the overall business objectives of the Company are rewarded with equity compensation, whereas performance tied to short-term goals of the Company, or individual performance, is rewarded with cash compensation. As different elements of the Company's compensation have different underlying rationale and policy, determinations the Compensation Committee made with regard to one compensation element have not influenced decisions it made with respect to other compensation elements it contemplated or awarded. For example, the factor that our Chief Executive Officer may receive a bonus if the performance objectives are satisfied and may receive additional value through his stock options if the Company's stock performs well has not influenced the determination as to the base salary of our Chief Executive Officer.

The Company's compensation philosophy was last reviewed by the Board in May 2007, at which time two new compensation programs were approved by the Board, the Incentive Bonus Program and the Annual Milestones bonus program. These two bonus programs were approved by the Board because they each met the Company's desire to reward and encourage executive officers and employees for not only causing the Company to meet its primary objectives but also to meet certain short-term objectives within a timeline prescribed by management. See "*Incentive Compensation*" below for details relating to these two programs.

#### **Role of the Compensation Committee**

The Compensation Committee currently consists of Messrs. John P. Brancaccio, Chairman, David Sidransky and Paul M. Weiss Ph.D. All committee members have been and currently are non-employee directors as defined under Rule 16b-3 of the Exchange Act and satisfy the director independence standards of the Nasdaq Stock Market and the definition of "outside director" under Section 162(m) of the Internal Revenue Code. No special expertise in compensation matters is required for appointment to the Compensation Committee.

The Compensation Committee is responsible for all components of the Company's executive compensation program and for administering all stock option plans including the 2004 Stock Incentive Plan, under which stock option grants may be made to executive officers. On an annual basis, the Compensation Committee reviews and approves the corporate goals and objectives relevant to the compensation for the Chief Executive Officer and other executive officers, if any. The Compensation Committee evaluates at least once a year, the Chief Executive Officer and executive officers' performance in light of these established goals and objectives and based upon these evaluations will set the Chief Executive Officer's and executive officers' annual compensation, including salary, bonus, incentive and equity compensation.

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#### **Role of Consultants and Market Review**

The Compensation Committee possesses the authority under its charter to hire advisors to provide it with information as needed in making compensation decisions. The Compensation Committee did not use a compensation consultant for fiscal 2011.

#### **Role of Management**

While the Compensation Committee determines overall compensation philosophy, it relies on the Chief Executive Officer and other executive officers, if any, to make recommendations in accordance with such compensation philosophy. The Company's Chief Executive Officer and Chief Financial Officer, if any, provide the Board and the Compensation Committee with feedback on the performance of the Company's non-executive officers and make compensation recommendations to the Compensation Committee for its approval.

Mr. Muniz was our only executive from April 3, 2009 to December 16, 2011. At the time he joined the Company, the Compensation Committee agreed to pay him a consulting fee of \$3,500 per week plus cost of travel between his home state of Florida and our office in New Jersey. On October 19, 2009, the Company entered into an Employment Agreement (the "Employment Agreement") with Mr. Muniz to serve as the Company's President, Chief Executive Officer and Chief Financial Officer. Under his Employment Agreement, Mr. Muniz will receive an annual base salary of \$300,000 plus cost of travel between his home state of Florida and our office in New Jersey and is entitled to receive cash incentive compensation or annual stock option awards as determined by the Board or the Compensation Committee of the Board from time to time. In addition, Mr. Muniz is entitled to participate in any and all employee benefit plans established and maintained by the Company for executive officers of the Company. Pursuant to the Employment Agreement, Mr. Muniz received an option (the "Option"), granted under and in accordance with the Company's 2004 Stock Incentive Plan, to purchase 500,000 shares of Common Stock exercisable for 10 years from the date the Option is granted. The Option shall vest in equal amounts on each of the first, second and third year anniversary of the grant so long as Mr. Muniz remains employed by the Company. The exercise price of the Option equals the fair market value of the Common Stock on the date of grant.

The Employment Agreement continues in effect for two years following the date of the agreement and automatically renews for successive one-year periods, unless Mr. Muniz's employment is terminated by him or by the Company. In the event that Mr. Muniz's employment is terminated by the Company for any reason, then Mr. Muniz is entitled to receive his earned but unpaid base salary and incentive compensation, unpaid expense reimbursements, accrued but unused vacation and any vested benefits under any employee benefit plan of the Company. In the event that Mr. Muniz's employment is terminated by the Company without "Cause" or by Mr. Muniz for "Good Reason" (as such terms are defined in the Employment Agreement), and provided Mr. Muniz executes a release in favor of the Company, then in addition to the above mentioned payments and benefits, Mr. Muniz is entitled to receive an amount equal to his then current annual base salary, payable in equal installments over 12 months in accordance with the Company's

payroll practice, and all medical and health benefits for 18 months following the termination date. In addition, in the event Mr. Muniz's employment is terminated without Cause or for Good Reason within 12 months following a Change in Control (as defined in the Employment Agreement), and provided Mr. Muniz executes a release in favor of the Company, in lieu of the severance described above, Mr. Muniz is entitled to receive a lump cash payment equal to his then current annual base salary, all medical and health benefits for 18 months following the termination date and full acceleration of vesting of all unvested stock options and other share-based awards. Mr. Muniz's Employment Agreement requires him to refrain from competing with the Company and from hiring our employees and soliciting our customers for a period of one year following the termination of his employment with the Company for any reason. The Employment Agreement was filed as Exhibit 10.5 to the Company's Form 8-K filed with the SEC on October 20, 2009.

On December 16, 2011, the Board determined that the employment of Charles Muniz, President, Chief Executive Officer and Chief Financial Officer of the Company, would end.

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On December 23, 2011, the Board appointed Lawrence A. Kenyon as interim Chief Executive Officer and Chief Financial Officer of the Company, effective immediately with a monthly salary of \$5,000.

On May 30, 2012, the Company was served with a complaint filed by its current board member and former President and Chief Executive Officer, Charles Muniz, in the Superior Court of New Jersey, Middlesex County. In the complaint Mr. Muniz alleges that his employment with the Company was wrongfully terminated and that such termination was in retaliation for his complaints to the Board. Mr. Muniz claims the Board failed to disclose material and significant information to investors and shareholders about ONCONASE® for HPV and that such failure to disclose such information constituted unlawful deception, misrepresentation, violation of the board's fiduciary responsibilities and fraudulent activity. Mr. Muniz is seeking unspecified damages. The Company believes Mr. Muniz's allegations are without merit and intends to defend itself from his claims to the extent it has the resources to do so.

#### **Executive Compensation Components**

Compensation for the Company's executive officers includes the following components:

Base Salary. Fixed annual compensation that is certain as to payment and provides continuous income to meet ongoing living costs. This component is intended to ensure that Tamir is able to retain executives capable of achieving the Company's strategic and business objectives. The Compensation Committee reviews executive officers' salaries annually and will make adjustments based on its expectations of that officer's performance as compared to the officer's actual performance and what the Compensation Committee's expectations are for that officer's future performance. Additionally, the Compensation Committee factors in cost of living adjustments as well as the Company's overall performance and stock performance. As described on our annual report on Form 10-K for fiscal year 2008, the Compensation Committee also utilized a study of market compensation levels prepared by an independent compensation consultant in order to evaluate the executive's compensation, including base salaries. Such a study was used by the Compensation Committee in setting base salaries for the Company's fiscal year 2008. Such study was not used in previous years, except for fiscal year 2008 and was not used in fiscal 2011.

In light on the Company's financial difficulties, lack of executive leadership and inability to conduct a thorough market-based analysis of executive compensation, the Compensation Committee determined that Mr. Muniz, the Company's sole executive officer, should receive the same base compensation package, in all material respects, as his predecessor, Kuslima Shogen.

Stock Option Grants. Long-term incentive plan which offers eligible Company officers and employees incentives to put forth maximum efforts for the success of the Company's business, to afford executive officers an opportunity to

acquire a proprietary interest in the Company and to relate the compensation of officers to the value they create for the Company's stockholders. Currently, all share-based awards are granted under the 2004 Stock Incentive Plan, which was approved by the Board of Directors and stockholders of the Company in November 2003 and in January 2004, respectively. The 2004 Stock Incentive Plan provides for the grant of stock options and other share-based awards to employees, officers, consultants, independent contractors and directors providing services to Tamir and its subsidiaries as determined by the Board or by the Compensation Committee. The types of awards that may be granted under the 2004 Stock Incentive Plan are stock options, stock appreciation rights, restricted stock, restricted stock units, performance awards, dividend equivalents, other stock grants, other share-based awards and any combination thereof. Stock options are granted based on the fair market value of a share on the date of grant of such option. The terms, time and method of the options are determined at the sole discretion of the Compensation Committee.

At the time he joined the Company in April 2009, Mr. Muniz did not receive any share-based compensation. After completion of the Company's financing in October 2009, pursuant to his Employment Agreement, Mr. Muniz received stock options to purchase 500,000 shares of Common Stock. The Compensation Committee determined this was an appropriate grant in light of prior grants made to the Company's former Chief Executive Officer, Mr. Muniz's success in obtaining financing for the Company in very difficult market conditions and the need to provide Mr. Muniz with additional incentive to create further value for the Company's stockholders.

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*Incentive Compensation.* The primary purpose is to align the interests of the executive officers with those of the stockholders by rewarding executive officers for creating stockholder value over the long-term. The 2004 Stock Incentive Plan provides for the award of stock options, stock appreciation rights, restricted stock, restricted stock units, performance awards, dividend equivalents, and other stock grants or stock based awards.

Other Benefits. The Chief Executive Officer is eligible to participate in the Company's 401(k) plan, health and dental coverage, life insurance, disability insurance, paid time off and paid holidays on the same terms as are available to all employees generally.

Post-termination Agreements. Other than severance payments provided for in Mr. Muniz's Employment Agreement and Ms. Shogen's Retirement Agreement, as described in the annual report on Form 10-K/A filed with the SEC on November 30, 2009, the Company does not utilize post-termination agreements. In addition, under grants awarded pursuant to the 2004 Stock Incentive Plan, the recipients of such grants have received Stock Option Agreements which contain provisions that allow for the awarded options to become fully vested and immediately exercisable or exercisable during the six months following a change in control but in no event beyond the option period provided in the Stock Option Agreement; provided, however, that the terms of Mr. Muniz's Employment Agreement, as described above, supersede the terms set forth in his Stock Option Agreement. Per the Company's standard Stock Option Agreement, a change in control is deemed to occur if (i) a person, as defined by Section 13(d) and 14(d) of the Exchange Act, becomes the beneficial owner, directly or indirectly, of securities representing 20% or more of the combined voting power of the Company's then outstanding shares (except that ownership by the McCash Family Limited Partnership must be 50% to qualify as a change in control); (ii) during any 12 month period, the individuals who were, at the beginning of such period, a majority of the Board cease to be a majority of the Board; (iii) the Company's stockholders approve a merger or consolidation with another corporation except where the Company remains in control after such merger or consolidation or where the merger or consolidation was effected to recapitalize the Company and no one person acquired more than 50% of the combined voting power of the Company; or (iv) the stockholders of the Company approve a plan of complete liquidation or enter into an agreement for the sale or disposition of all or substantially all of the assets of the Company.

Additionally, under the terms of the Stock Option Agreements issued under the 2004 Stock Incentive Plan, if there is a termination of service due to the death, total disability or retirement of the optionee on or after age 65 after seven years of service with the Company, then the options become fully exercisable at the time of death, total disability or retirement, as the case may be, and may be exercised by the optionee or optionee's estate during the six months following the month of optionee's death, total disability or retirement but in no event beyond the option period provided in the Stock Option Agreement. If there is a termination of employment due to voluntary resignation then to the extent options are exercisable as of the date of the termination, such options may be exercised within six months of the date of termination of employment. If there is termination for cause, then to the extent options are exercisable as of the date of the termination, such options may be exercised within 30 days of the date of termination. "Cause" is defined as (i) frequent and unjustifiable absenteeism other than optionee's illness or physical or mental disability; (ii) fraud or dishonesty materially injurious to the Company; (iii) gross or willful misconduct or willful neglect to act which is committed or omitted by optionee in bad faith; (iv) gross breach of optionee's fiduciary duties which has a materially injurious effect on the Company; (v) optionee's conviction as a felon; or (vi) optionee's willful or continuous neglect or refusal to perform his or her duties. If there is termination for any reason other than those described above, then to the

extent options are exercisable as of the date of the termination, such options may be exercised within 12 months of the date of termination of employment.

Under grants awarded pursuant to the Company's 1997 and 1993 Stock Option Plans, prior to a dissolution or liquidation of the Company or a merger or consolidation where the Company is not the surviving corporation, the optionee has the right to exercise all outstanding options. If the optionee terminates employment, then to the extent options are exercisable as of the date of termination, such options may be exercised within 190 days of the date of termination of employment. If the Board determines that the optionee engaged in activities or employment contrary to the best interest of the Company, then the Board can cancel the options within 190 days of the termination of employment. If an optionee dies while still in service to the Company, then to the extent options are exercisable as of the date of death, such options may be exercised.

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The rationale for the acceleration of the options under the 2004 Stock Incentive Plan, and the 1997 and 1993 Stock Option Plans upon a change in control of the Company is to ensure that officers are motivated to pursue creating or obtaining the maximum value for stockholders and to encourage officers to remain with the Company after a change in control has occurred.

The following table summarizes the estimated value of the stock options for the executive officer derived from the terms of the 2004 Stock Incentive Plan, assuming that a triggering event took place on the last business day of our most recently completed fiscal year, July 31, 2011 and that the price per share of our common stock is the closing market price as of that date.

Name	Death or Total Disability <sup>(1)</sup>	Voluntary Termination or Termination for Cause <sup>(1)</sup>	Change in Control <sup>(1)</sup>
Charles Muniz	\$0	\$0	\$0

These amounts represent the aggregate in-the-money value of stock options based on a closing stock price of \$0.11 on July 31, 2011 which would become vested as a direct result of the termination event or change in control before the applicable stated vesting date. The stated vesting date is the date at which an award would have vested absent such termination event or change in control. This calculation of value does not attribute any additional value to stock options based on their remaining terms and does not discount the value of awards based on the portion of the vesting period elapsed at the date of the termination event or change in control.

*Pension Plans*. The Company does not have pension plans for its employees, executive officers or directors.

*Non-Qualified Deferred Compensation Plans*. The Company does not have non-qualified deferred compensation plans for its employees, executive officers or directors.

#### **Tax and Accounting Considerations**

Deductibility of Executive Compensation. In making compensation decisions affecting the executive officers, the Compensation Committee considers the Company's ability to deduct under applicable federal corporate income tax law compensation payments made to executives. Specifically, the Compensation Committee considers the requirements and impact of Section 162(m) of the Internal Revenue Code, which generally disallows a tax deduction for annual compensation in excess of \$1 million paid to our named executive officers. Certain compensation that qualifies under applicable tax regulations as "performance-based" compensation is specifically exempted from this deduction rule. The Compensation Committee cannot assure that it will be able to fully deduct all amounts of compensation paid to persons who are named executive officers in the future. Further, because the Compensation Committee believes it is important to preserve flexibility in designing its compensation programs, it has not adopted a policy that all compensation must qualify as deductible under Section 162(m). The cash compensation that the Company paid to each of its named executive officers during 2011 was below \$1 million. We believe that stock

options granted under the 2004 Stock Incentive Program would qualify as "performance-based compensation" and therefore are Section 162(m) qualified.

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#### **Summary Compensation Table**

The following table provides a summary of cash and non-cash compensation for each of the last two fiscal years ended July 31, 2011 and 2010.

Name and Principal Position	Year	Salary	Bonus	Ċ.	Option s Awards	Incentiv Plan	ui <b>N</b> on-Qua ve Deferred Compens ns <b>Æaimi</b> ngs		r ·satio	Total n <sup>(2)</sup>
		(\$)	(\$)	<b>(\$)</b> <sup>(1)</sup>	<b>(\$)</b> <sup>(1)</sup>	F	(\$)			(\$)
Charles Muniz	2011	323,076	_		_	_	_	30,698	(5)	353,774
President, Chief Executive Officer and Chief Financial Officer <sup>(3)</sup>	2010	\$275,038(4)	_	_	\$142,500	_	_	\$ 23,521	(5)	\$441,059

These amounts represent the dollar amount recognized for financial statement reporting purposes the grant date fair value of stock options granted to the named executive officers in accordance with the FASB amended guidance on accounting for Stock Compensation. The grant date fair value was estimated using the Black-Scholes stock option

<sup>(1)</sup> pricing model in accordance with the FASB amended guidance on accounting for Stock Compensation. Pursuant to the SEC rules, the amounts exclude the impact of estimated forfeitures related to service-based vesting conditions. Valuation assumptions used in the calculation are as disclosed in this annual report on Form 10-K for the year ended July 31, 2011.

<sup>(2)</sup> Excludes perquisites and other personal benefits that in the aggregate do not exceed \$10,000.

Mr. Muniz served as the Company's President, Chief Operating Officer, Chief Financial Officer and director to the Board from April 3, 2009 until December 16, 2011 where he was replaced by Lawrence A. Kenyon. Mr. Muniz initially began consulting with the Company on February 9, 2009. On April 3, 2009, Mr. Muniz was appointed as the Company's President, Chief Operating Officer and Chief Financial Officer. Given the Company's difficult financial condition, Mr. Muniz continued to receive consulting payments from the date he first began

consulting with the Company continuing through October 19, 2009. These amounts represent consulting fee from August 1, 2009 to October 16, 2009 which amounted to \$38,500 and his wages from October 19, 2009 to July 31, 2010 amounted to \$236,538.

This amount consists of travel cost and reimbursements totaling \$14,567 and \$9,550 and health insurance reimbursement of \$16,131 and \$13,971 for fiscal 2011 and 2010.

#### **Grants of Plan-Based Awards in Fiscal 2011**

During fiscal 2011, no stock options under equity and non-equity incentive plans were granted to the Executive Officer.

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#### **Outstanding Equity Awards at Fiscal Year-End**

The following table sets forth the information with respect to the Executive Officer concerning the exercisable and unexercisable stock option awards held as of July 31, 2011<sup>(1)</sup>:

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price (\$)	Option Expiration Date
Charles Muniz	166,650	333,350	-	\$0.34	10/19/19

The Company does not have stock awards as part of its compensation program, therefore the columns entitled "Stock Awards" have been omitted from this table.

#### **Option Exercises and Stocks Vested**

The Named Executive Officers did not exercise options during fiscal 2011.

#### **Non-Employee Directors' Compensation**

In February 2007, the Board adopted a non-employee director compensation policy whereby each member of the Board who was not an employee of Tamir will receive \$15,000 per year in consideration of the member's serving on the Board, payable in four equal quarterly installments. This cash compensation ceased in January 2009. In addition, each non-employee director will be granted an annual retainer of 20,000 options on the last trading day of December for each year under the 2004 Stock Incentive Plan. The Chairman of the Board will receive an option bonus equal to the number of options received by the Chairman for his board and committee memberships. Committee chairpersons receive 10,000 options for each committee chaired while each committee member receives 5,000 options for each committee on which he serves. The exercise price of the options will be equal to the closing price of the Common Stock on the date of the grant. The options will vest on the first anniversary of the date of the grant provided that the option holder remains a director as of such anniversary date and the options will terminate on the sixth anniversary of the date of the grant.

Under our director compensation policies, directors who also serve as executive officers do not receive additional compensation for their service on our Board.

The exercise price and vesting schedules for the regular and discretionary option grants described above are set forth in the table titled "*Directors' Stock Options*" below. The total compensation paid to independent directors for their service as directors of the Company for fiscal 2011 is set forth in the table titled "*Directors' Compensation*" below.

During fiscal 2011, the following independent or non-employee directors were compensated as follows for their service as directors of the Company:

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#### **Directors' Stock Options**

During fiscal 2011, the following independent or non-employee directors were granted options under Tamir's 2004 Stock Incentive Plan as described above:

Name	<b>Number of Options Granted</b>	<b>Exercise Price of Options Granted</b>
John P. Brancaccio	125,000 (1)(2)	\$0.12
David Sidransky, M.D.	180,000(1)(3)	\$0.12
Paul M. Weiss, Ph.D.	$125,000^{(1)(4)}$	\$0.12

All the options listed here were granted on June 6, 2011 and vested on December 31, 2011, provided that the option (1) holder continuously remained a director until such time, and expire on December 31, 2016. The exercise price of these options was the closing price of the Company's Common Stock on the date of the grant.

Mr. Brancaccio's options are the result of his serving on the as Chairman of the Audit and Compensation Committees.

Dr. Sidransky's options are the result of his serving as Chairman of the Board, Chairman of the Corporate

- (3) Governance and Nominating Committee, Chairman of the Research and Clinical Oversight Committee and a member of the Commercial and Business Development Oversight Committee.
- Dr. Weiss' options are the result of his serving on the Compensation Committee, the Corporate Governance and Nominating Committee, the Audit Committee, the Research and Clinical Oversight Committee.

#### **Directors' Compensation**

During fiscal 2011, the following independent or non-employee directors were compensated as follows for their service as directors of the Company:

Name	Fees Earned or Paid in Cash (\$)	Stock Awards <sup>(1)</sup> (\$)	Option Awards <sup>(1)</sup> (\$)	Non-Equity Incentive Plan Compensation (\$)	Change in Pension Value and Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
John P. Brancaccio	\$ 0	-	\$11,638	-	-	-	\$11,638
David Sidransky, M.D.	\$0	-	\$16,758	-	-	-	\$16,758

Paul Weiss, \$ 0 - \$11,638 - - \$11,638

These amounts represent the dollar amount recognized for financial statement reporting purposes for the fair value of stock options granted to non-employee directors for fiscal 2011. The grant date fair value of the options was estimated using the Black-Scholes stock option pricing model. Valuation assumptions used in the calculation are as disclosed in this annual report on Form 10-K for the year ended July 31, 2011.

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#### **Outstanding Equity Awards at Fiscal Year-End**

The following table sets forth the information with respect to the independent or non-employee directors concerning exercisable and unexercisable stock options held as of July 31, 2011<sup>(1)</sup>:

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
	20,000	-	1.89	12/30/11
	20,000	-	1.60	12/30/12
	15,000	-	1.49	02/08/13
John P.	35,000	-	1.72	12/31/13
	35,000	-	0.24	12/31/14
Brancaccio	125,000	-	0.26	12/31/15
	-	$125,000^{(2)}$	0.12	12/31/16
	20,000	-	1.89	12/30/11
	20,000	-	1.60	12/30/12
David	70,000	-	1.49	02/08/13
Sidransky,	90,000	-	1.72	12/31/13
M.D.	90,000	-	0.24	12/31/14
	180,00	-	0.26	12/31/15
		180,000(2)	0.12	12/31/16
	20,000	-	1.89	12/30/11
	20,000	-	1.60	12/30/12
Paul M. Weiss	30,000	-	1.49	02/08/13
Ph.D.	5, 50,000	-	1.72	12/31/13
ΓII.D.	50,000	-	0.24	12/31/14
	125,000	-	0.26	12/31/15
	-	$125,000^{(2)}$	0.12	12/31/16

These options vested on December 31, 2011.

#### REPORT OF THE COMPENSATION COMMITTEE OF THE BOARD OF DIRECTORS

The Company does not have stock awards as part of its compensation program, therefore the columns entitled "Stock Awards" have been omitted from this table.

The Compensation Committee has overall responsibility for evaluating and approving the Company's executive officer compensation plans, policies and programs, including compensation of the Chief Executive Officer. During fiscal 2011 the Compensation Committee consisted of three independent directors. Our compensation program, both for our executive officers as well as for all employees, is based on the philosophy that the interests of our employees should be closely aligned with those of our stockholders. As with many other biotechnology companies, Tamir's current level of development and the highly volatile nature of biotechnology stocks in general makes executive compensation, which is normally based on sales and earnings goals, or strictly based on stock performance, impracticable. In determining compensation, the Compensation Committee generally reviews the progress made by the individual officer in attaining his or her individual goals and the progress made by the Company in its drug development programs. In addition, the Compensation Committee keeps the Company's stock performance in mind when making compensation decisions. Finally, the Compensation Committee generally reviews and takes into account competitive factors regarding compensation. Our compensation program is based on the following principles:

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- · Compensation opportunities should attract the best talent, motivate individuals to perform at their highest levels, reward outstanding achievement, and retain the leadership and skills necessary for building long-term stockholder value:
  - · Compensation should include a bonus potential which is tied directly to operating objectives; and
- · Compensation should include a long-term incentive award generally in the form of stock option grants to increase ownership in the Company and encourage executives to manage from the perspective of owners of the Company.

The Compensation Committee has reviewed and discussed the Compensation Discussion and Analysis as required by Item 402(b) of Regulation S-K with management. Based on these reviews and discussions, the Compensation Committee recommended to the Board of Directors that the Compensation Discussion and Analysis be included in the Company's annual meeting proxy statement on Schedule 14A.

This report is respectfully submitted by the members of the Compensation Committee of the Board.

John P. Brancaccio, Chairman

David Sidransky, M.D.

Paul M. Weiss, Ph.D.

# ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

#### **Security Ownership of Certain Beneficial Owners**

Amount and Nature of Beneficia Ownership	IPercent of Shares Outstanding <sup>(1)</sup>
244,802,762	43.8%
26,514,989 132,574,947	6.4% 27.3%
	Ownership 244,802,762 26,514,989

W-Net Fund I LP, W=Net Fund GP I LLC, and David 44,191,645
Weiner (3) 10.4%

The percentage of stock outstanding for each stockholder is calculated by dividing (i) the number of shares deemed to be beneficially held by such stockholder as of the date of the calculation by (ii) the sum of (A) the number of

- (1) shares of Common Stock outstanding as of the date of the calculation, plus (B) the number of shares issuable upon conversion of securities convertible into shares of Common Stock and upon exercise of options or warrants held by such stockholder.
- Knoll Capital Management LP, Fred Knoll and Europa International, Inc. filed a Form3 on December 14, 2012 with the SEC as joint filers.
- (3) W-Net Fund I LP, W=Net Fund GP I LLC. filed a schedule 13D on February 5, 2013 with the SEC as joint filers.

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#### **Security Ownership of Management**

Name and Address of Beneficial Owner or Identity of Group <sup>(1)</sup>	Position	Amount and Nature of Beneficial Ownership <sup>(2)</sup>	Percent of Shares Outstanding <sup>(3)</sup>
Jamie Sulley	President, Chief Executive Officer and Director	<sup>e</sup> 16,902,667	4.3%
Joanne Barsa	Chief Financial Officer	-	-
John P. Brancaccio	Director	701,300	0.2%*
Fred Knoll	Director	244,802,762 <sup>(4)</sup>	43.8%
Francis Patrick Ostronic	Director	-	0.0%*
David Sidransky, M.D.	Chairman of the Board	1,125,000	0.3%*
Paul M. Weiss, Ph.D.	Director	765,090	0.2*
All Named Executive Officers and directors as a group (7 persons)		264,296,819 <sup>(5)</sup>	48.74%

Unless otherwise indicated below, the persons in the above table have sole voting and investment power with (1) respect to all shares beneficially owned by them. The address of all Named Executive Officers and directors is c/o Tamir Biotechnology, Inc., 12750 High Bluff Dr., Suite 190, San Diego, CA 92130.

All shares listed are Common Stock. Except as discussed below, none of these shares are subject to rights to acquire beneficial ownership, as specified in Rule 13d-3(1) under the Exchange Act, and the beneficial owner has sole voting and investment power, subject to community property law where applicable. The information presented in

(2) this table is based on 217,364,331 shares of our common stock and preferred shares convertible into 177,185,200 shares of our common stock on April 25, 2013.

The percentage of stock outstanding for each stockholder is calculated by dividing (i) the number of shares deemed (3) to be beneficially held by such stockholder by (ii) the sum of (A) the number of shares of Common Stock outstanding plus (B) the number of shares issuable upon exercise of options or warrants held by such stockholder.

Knoll Capital Management LP, Fred Knoll and Europa International, Inc. filed a Form3 on December 14, 2012 with the SEC as joint filers.

(5) Includes all shares owned beneficially by the directors and the executive officers named in the table.

The following table provides information as of July 31, 2011 on our equity based compensation plans that may be issued upon the exercise of stock options:

Number of Securities Remaining Available for Future Issuance under

 $<sup>^{\</sup>ast}\,$  Represents less than 1% of Tamir's outstanding Common Stock.

**Equity Compensation Plans** (Excluding Securities Reflected in

Number of Securities to Weighted-average Exercise Column (a))

be Issued upon Exercise of Price of Outstanding Outstanding Options, Options, Warrants and

Warrants and Rights Rights

**Plan Category** 

(a) (b) (c)

Equity compensation plans approved by

security holders 3,854,867 \$ 1.21 4,705,333

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# ITEM 13. <u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR</u> INDEPENDENCE.

#### **Related Party Transactions**

The Company recognizes that related party transactions can create the appearance that Company decisions are made based on factors other than the Company's best interest or the best interest of the Company's stockholders. Related party transactions can also create potential or actual conflicts of interest between the Company and the related party. For purposes of Item 404 of Regulation S-K, related person transactions are transactions which exceed \$120,000 in the aggregate or 1% of the average of the Company's total assets at year end for the last three completed fiscal years, to which the Company and a related party with a direct or indirect material interest, participated. The Company's Code of Business Conduct and Ethics requires that any such related party transactions be specifically approved by the Audit Committee. In addition directors, officers and employees must notify the Ethics Officer or the Chair of the Audit Committee of the existence of any actual or potential conflicts of interest. The Audit Committee performs a review of related party transactions as part of its review of the annual report on Form 10-K for the fiscal year ended July 31, 2011.

The Company was a party to the following transactions in which the amount involved exceeded \$120,000 and in which any executive officers, directors, holders of more than 5% of our capital stock and members of such person's immediate families had or will have a direct or indirect material interest.

On October 20, 2009, the Company completed a sale of 65 units (the "Units") in a private placement (the "Offering") to certain investors pursuant to a securities purchase agreement entered into on October 19, 2009. Each Unit consists of (i) \$50,000 principal amount of 5% Senior Secured Convertible Promissory Notes (collectively, the "Notes") convertible into shares of the Company's Common Stock, (ii) Series A Common Stock Purchase Warrants (the "Series A Warrants") to purchase in the aggregate that number of shares of Common Stock initially issuable upon conversion of the aggregate amount of Notes issued as part of the Unit, at an exercise price of \$0.15 per share with a three year term and (iii) Series B Common Stock Purchase Warrants (the "Series B Warrants" and together with the Series A Warrants, the "Warrants") to purchase in the aggregate that number of shares of Common Stock initially issuable upon conversion of the aggregate amount of Notes issued as part of the Unit, at an exercise price of \$0.25 per share with a five year term. The closing of the Offering occurred on October 19, 2009 and the Company received an aggregate of \$3,250,000 in gross proceeds. Charles Muniz, the Company's President, Chief Executive Officer, Chief Financial Officer and Director, subscribed for 20 Units, certain trusts and individuals related to James O. McCash, Europa International Inc., an affiliate of Knoll Capital Management LP, subscribed for 15 Units.

#### **Director Independence**

Please see the sections entitled *Independent Directors* and *Board Committee Membership* in Item 10 "Directors, Executive Officers and Corporate Governance" above for disclosures on Board independence and committee membership.

#### ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

In accordance with the requirements of the Sarbanes-Oxley Act of 2002 and the Audit Committee Charter, all audit and audit-related work and all non-audit work performed by the independent registered public accounting firm is approved in advance by the Audit Committee, including the proposed fees for such work. The Audit Committee is informed of each service actually rendered that was approved through its pre-approval process.

On March 25, 2013, we dismissed CohnReznick LLP (f/k/a J.H. Cohn LLP) ("CohnReznick") as the Company's independent registered public accounting firm.

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The audit report of CohnReznick on the financial statements of the Company as of July 31, 2010 and 2009 and for the years then ended, which are the most recent fiscal years for which the Company has audited financial statements, did not contain any adverse opinion or disclaimer of opinion, nor was such report qualified or modified as to uncertainty, audit scope or accounting principles, except that such report included an explanatory paragraph relating to our ability to continue as a going concern.

During the years ended July 31, 2010 and 2009, and through the date of their dismissal, there were no disagreements between the Company and CohnReznick as to any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of CohnReznick, would have caused CohnReznick to make reference in their reports on the financial statements for such years to the subject matter of the disagreement.

On March 25, 2013, we engaged Goldman Kurland and Mohidin LLP ("GKM"), as its independent accountants to audit the Company's financial statements for its fiscal years ended July 31, 2011, 2012 and 2013. In the Company's two most recent fiscal years and subsequent interim periods prior to such engagement, the Company has not (itself or through someone acting on its behalf) consulted with GKM on either (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's financial statements, or (ii) any matter that was either the subject of a disagreement, as that term is defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions to Item 304 of Regulation S-K, or a reportable event, as that term is defined in Item 304(a)(1)(v) of Regulation S-K.

#### **Audit Fees**

Audit fees expensed by Tamir to J.H. Cohn LLP for the audit of the financial statements included in Tamir's annual report on Form 10-K, auditors' review of the financial statements included in Tamir's Quarterly Reports on Form 10-Q, work related to Tamir's registration statements and consultation on accounting topics for the years ended July 31, 2011 and 2010 totaled approximately \$68,000 and \$124,000, respectively.

Audit-related F
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None.

#### **Tax Fees**

None.
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#### **All Other Fees**

None.

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#### Part IV

3.6

3.7

3.8

#### Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

The response to these portions of Item 15 is submitted as a separate section of this report commencing (a)(1) and on page F-1 (2) Exhibits (numbered in accordance with Item 601 of Regulation S-K). (a)(3)Filed Herewith or Incorporated by Reference Exhibit No. Item Title Certificate of Incorporation, dated June 12, 1981 (incorporated by reference to 3.1 Exhibit 3.1 to the Company's Registration Statement on Form S-1, File No. 333-112865, filed on February 17, 2004) Amendment to Certificate of Incorporation, dated February 18, 1994 (incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-1, 3.2 File No. 333-112865, filed on February 17, 2004) Amendment to Certificate of Incorporation, dated December 26, 1997 (incorporated 3.3 by reference to Exhibit 3.3 to the Company's Registration Statement on Form S-1, File No. 333-112865, filed on February 17, 2004) Amendment to Certificate of Incorporation, dated January 14, 2004 (incorporated by reference to Exhibit 3.4 to the Company's Registration Statement on Form S-1, File \* 3.4 No. 333-112865, filed on February 17, 2004) Certificate of Designation for Series A Preferred Stock, dated September 2, 2003 (incorporated by reference to Exhibit 3.5 to the Company's Registration Statement on\* 3.5 Form S-1, File No. 333-112865, filed on February 17, 2004)

Certificate of Elimination of Series A Preferred Stock, dated February 3, 2004

Certificate of Amendment to Certificate of Incorporation, dated April 27, 2010

Form S-1, File No. 333-112865, filed on February 17, 2004)

8-K, filed on April 30, 2010)

(incorporated by reference to Exhibit 3.6 to the Company's Registration Statement on\*

(incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form \*

	By-Laws (incorporated by reference to Exhibit 3.4 to Registration Statement on	
	Form S-1, File No. 333-111101, filed on December 11, 2003)	
	Certificate of Designations, Powers Preferences and Rights of the Series A	
3.9	Convertible Preferred Stock of the Company (incorporated by reference to Exhibit	*
	3.1 to Form 8-K filed on December 19, 2012)	
4.1	Form of Note	*
4.2	Form of Series A Common Stock Purchase Warrant	*
4.3	Form of Series B Common Stock Purchase Warrant	*
4.4	Form of Warrant (incorporated by reference to Exhibit 4.1 to Form 8-K filed on	*
4.4	December 19, 2012)	•
	1993 Stock Option Plan and Form of Option Agreement (incorporated by reference	
10.1	to Exhibit 10.10 to Registration Statement on Form SB-2, File No. 33-76950, filed	*
	on August 1, 1994)	
10.2	1997 Stock Option Plan (incorporated by reference to Exhibit 10.2 to Registration	*
10.2	Statement on Form S-1, File No. 333-111101, filed on December 11, 2003)	•
10.2.1	Amendment No. 1 to 1997 Stock Option Plan (incorporated by reference to Exhibit	*
10.2.1	10.2.1 to the Company's Quarterly Report on Form 10-Q, filed on June 9, 2008)	-1-

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- 10.3 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement, on Form S-1, File No. 333-112865, filed on February 17, 2004)
- Amendment No. 1 to 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.3.1 to the Company's a Quarterly Report on Form 10-Q, filed on June 9, 2008)

Form of Subscription Agreement and Warrant Agreement used in Private Placements completed in February

10.4 2000 (incorporated by reference to Exhibit 10.21 to the Company's annual report on Form 10-K, filed on October 30, 2000)
 Form of Subscription Agreement and Warrant Agreement used in the August and September 2000 Private

10.5 Placements (incorporated by reference to Exhibit 10.24 to the Company's Quarterly Report on Form 10-Q, filed on December 15, 2000)

Form of Subscription Agreement and Warrant Agreement used in the April 2001 Private Placements

- 10.6 (incorporated by reference to Exhibit 10.23 to Registration Statement on Form S-1, File No. 333-38136, filed \* on July 30, 2001)
- Form of Convertible Note entered into in April 2001 (incorporated by reference to Exhibit 10.24 to Registration Statement on Form S-1, File No. 333-38136, filed on July 30, 2001)
  Form of Subscription Agreement and Warrant Agreement used in the July 2001 Private Placements
- 10.8 (incorporated by reference to Exhibit 10.25 to Registration Statement on Form S-1, File No. 333-38136, filed \* on July 30, 2001)
- Form of Subscription Agreement and Warrant Agreement used in the August and October 2001 private placement (incorporated by reference to Exhibit 10.26 to Registration Statement on Form S-1, File No. 333-38136, filed on December 14, 2001)
- Form of Subscription Agreement and Warrant Agreement used in the September 2001, November 2001 and 10.10 January 2002 private placements (incorporated by reference to Exhibit 10.27 to Registration Statement on Form S-1, File No. 333-38136, filed on February 21, 2002)
- Warrant issued in the February 2002 private placement (incorporated by reference to Exhibit 10.28 to Registration Statement on Form S-1, File No. 333-38136, filed on February 21, 2002)
  Form of Subscription Agreement and Warrant Agreement used in the March 2002, April 2002 and May 2002
- 10.12 private placements (incorporated by reference to Exhibit 10.29 to Registration Statement on Form S-1, File No. 333-89166, filed on May 24, 2002)
   Form of Subscription Agreement and Warrant Agreement used in the June 2002 and October 2002 private
- 10.13 placements (incorporated by reference to Exhibit 10.30 to the Post-Effective Amendment to Registration Statement on Form S-1, File No. 333-38136, filed on March 3, 2003)

  Form of Note Payable and Warrant Certificate entered into April, June, July, September, November and
- 10.14 December 2002 (incorporated by reference to Exhibit 10.31 to the Post-Effective Amendment to Registration \* Statement on Form S-1, File No. 333-38136, filed on March 3, 2003)

  Form of Note Payable and Warrant Certificate entered into November 2001, January, March and May 2003
- 10.15 (incorporated by reference to Exhibit 10.23 to the Company's annual report on Form 10-K, filed on October \$29, 2003)
  - Form of Subscription Agreement and Warrant Agreement used in the February 2003 and April through
- 10.16 August 2003 private placements (incorporated by reference to Exhibit 10.24 to the Company's annual report on Form 10-K, filed on October 29, 2003)

\*

Form of Amended Notes Payable which amends the November 2001, April 2002, June 2002, July 2002, September 2002, November 2002 December 2002, January 2003, March 2003 and May 2003 notes payable (incorporated by reference to Exhibit 10.27 to The Company's annual report on Form 10-K, filed on October 29, 2003)

Securities Purchase Agreement and Warrant Agreement used in September 2003 private placement and Form of Warrant Certificate issued on January 16, 2004 and January 29, 2004 to SF Capital Partners Ltd.

(incorporated by reference to Exhibit 10.25 to the Company's annual report on Form 10-K, filed on October 29, 2003)

Registration Rights Agreement used in September 2003 private placement with SF Capital Partners Ltd. 10.19 (incorporated by reference to Exhibit 10.26 to the Company's annual report on Form 10-K, filed on October 29,\* 2003)

Form of Securities Purchase Agreement used in May 2004 private placement with Knoll Capital Fund II, 10.20 Europa International, Inc. and Clifford and Phyllis Kalista JTWROS (incorporated by reference to Exhibit 4.3 to Registration Statement on Form S-1, File No. 333-112865, filed on May 18, 2004)

Form of Registration Rights Agreement used in May 2004 private placement with Knoll Capital Fund II, 10.21 Europa International, Inc. and Clifford and Phyllis Kalista JTWROS (incorporated by reference to Exhibit 4.4 to Registration Statement on Form S-1, File No. 333-112865, filed on May 18, 2004)

Form of Warrant Certificate issued on May 11, 2004 to Knoll Capital Fund II, Europa International, Inc. and 10.22 Clifford and Phyllis Kalista JTWROS (incorporated by reference to Exhibit 4.5 to Registration Statement on Form S-1, File No. 333-112865, filed on May 18, 2004)

Form of Stock Option Agreement issued to the Company's Board of Directors under the Company's 1997 Stock 10.23 Option Plan (incorporated by reference to Exhibit 10.23 to the Company's quarterly report on Form 10-Q filed on June 9, 2005)

Form of Stock Option Agreement issued to the Company's Executive Officers under the Company's 1997 Stock 10.24 Option Plan (incorporated by reference to Exhibit 10.24 to the Company's quarterly report on Form 10-Q filed on June 9, 2005)

Separation Agreement and General Release with Andrew Savadelis dated May 26, 2005 (incorporated by reference to Exhibit 10.25 to the Company's annual report on Form 10-K, filed on October 15, 2005)

Securities Purchase Agreement used in May 2005 private placement with Jeffrey D'Onofrio dated May 1, 2006 10.26 (incorporated by reference to Exhibit 10.26 to the Company's annual report on Form 10-K, filed on October 16, 2006)

10.27 Form of Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed on July 19, 2006)

Registration Rights Agreement dated July 17, 2006 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed on July 19, 2006)

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10.29	Agreement to Amend Knoll Warrant dated July 17, 2006 (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K, filed on July 19, 2006)	;
10.30	Form of Amended Knoll Warrant (incorporated by reference to Exhibit 4.4 to the Company's Current Report of Form 8-K, filed on July 19, 2006)	n:
10.31	Agreement to Amend SF Capital Warrant dated July 17, 2006 (incorporated by reference to Exhibit 4.5 to the Company's Current Report on Form 8-K, filed on July 19, 2006)	;
10.32	Form of Amended Warrant for SF Capital Partners, Ltd. (incorporated by reference to Exhibit 4.6 to the Company's Current Report on Form 8-K, filed on July 19, 2006)	:
10.33	Securities Purchase Agreement dated July 17, 2006 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on July 19, 2006)	:
10.34	Form of Stock Option Agreement for Executive Officers under the Company's 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.34 to the Company's Quarterly Report on Form 10-Q, filed on March 12, 2007)	;

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Offer letter agreement with Lawrence A. Kenyon dated January 16, 2007 (incorporated by reference to Exhibit 10.35 to the Company's Quarterly Report on Form 10-Q, filed on March 12, 2007)	*
10.36 Summary of the Company's Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.36 to the Company's Quarterly Report on Form 10-Q, filed on March 12, 2007)	*
Royalty Agreement between the Company and Kuslima Shogen, dated July 24, 1991 and Amendment to	
10.37 Royalty Agreement, dated April 16, 2001 (incorporated by reference to Exhibit 10.37 to the Company's	*
Quarterly Report on Form 10-Q, filed on March 12, 2007)	
Office Lease Agreement, dated March 14, 2007, between I&G Garden State, LLC and the Company	
10.38 (incorporated by reference to Exhibit 10.38 to the Company's Quarterly Report on Form 10-Q, filed on Jun 18, 2007)	k
Form of Distribution and Marketing Agreement, dated July 25, 2007, between the Company and USP Phar	
10.39 Spolka Z.O.O. (incorporated by reference to Exhibit 10.39 to the Company's Quarterly Report on Form 10 filed on October 15, 2007)	-Q, ,
Form of Securities Purchase Agreement, dated July 25, 2007, between the Company and Unilab LP.	
10.40 (incorporated by reference to Exhibit 10.40 to the Company's Quarterly Report on Form 10-Q, filed on	
October 15, 2007)	*
License Agreement, dated January 14, 2008, between the Company and Par Pharmaceutical, Inc.	
10.41 (incorporated by reference to Exhibit 10.41 to the Company's Quarterly Report on Form 10-Q, filed on Ma 7, 2008)	arch *
Supply Agreement, dated January 14, 2008, between the Company and Par Pharmaceutical, Inc.	
10.42 (incorporated by reference to Exhibit 10.42 to the Company's Quarterly Report on Form 10-Q, filed on Ma 7, 2008)	arch*
Purchase and Supply Agreement, dated January 14, 2008, between the Company and Scientific Protein 10.43 Laboratories LLC (incorporated by reference to Exhibit 10.43 to the Company's Quarterly Report on Form 10-Q, filed on March 7, 2008)	1
Amendment No. 1 to 1993 Stock Option Plan (incorporated by reference to Exhibit 10.44 to the Company Quarterly Report on Form 10-Q, filed on June 9, 2008)	's *
Retirement Agreement, dated April 25, 2008, between the Company and Kuslima Shogen (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K, filed on April 28, 2008)	/ *
Securities Purchase Agreement dated October 19, 2009 by and among the Company and the investors nam 10.46therein (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on	
October 20, 2009)	k
Amendment to Securities Purchase Agreement dated February 26, 2010 by and among the Company and the 10.47 investors named therein (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Fo	
8-K, filed on March 4, 2010)	)1111 *
Investors Rights Agreement dated October 19, 2009 by and among the Company and the investors named	
10.48 therein (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on	
October 20, 2009)	*
Amendment to Investor Rights Agreement dated February 26, 2010 by and among the Company and the	
10.49 investors named therein (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Fo	orm
8-K, filed on March 4, 2010)	*
Security Agreement dated October 19, 2009 by and among the Company, the agent named therein and the	
10.50 secured parties named therein (incorporated by reference to Exhibit 10.3 to the Company's Current Report	on
Form 8-K, filed on October 20, 2009)	*
10.51 Escrow Agreement by and among the Company and the parties named therein dated October 19, 2009 (incorporated by reference to Exhibit 10.4 to the Company's Current Report 8-K, filed on October 20, 2009	9)

\*

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10.52	Employment Agreement by and between the Company and Charles Muniz dated October 19, 2009 (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K, filed on October 20, 2009)	* ^
10.53	Termination Agreement between the Company and Par Pharmaceutical, Inc. (incorporated by reference to Exhibit 10.51 to the Company's Quarterly Report on Form 10-Q, filed on November 13, 2009)	*
10.54	Amendment to the Retirement Agreement, dated April 25, 2008, between the Company and Kuslima Shogen (incorporated by reference to Exhibit 10.52 to the Company's Quarterly Report on Form 10-Q, filed on November 13, 2009)	*
	Amendment to each 5% Senior Secured Convertible Promissory Note by and between the Company and the holders thereof dated February 26, 2010 (incorporated by reference to Exhibit 10.2 to the Company's Current's Report on Form 8-K, filed on March 4, 2010)	*
	Amendment to Investors Rights Agreement dated July 31, 2010 by and among the Company and the investors named therein	+
10.57	Office Lease Agreement, dated September 28, 2010, between Princeton Corporate Plaza, LLC and the Company	+
	Memorandum of Understanding between the Company and US Pharmacia International, Inc. dated January 13, 2012 (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K, filed on 'Appears' 13, 2012)	*
	Securities purchase agreement, dated as of December 11, 2012 (incorporated by reference to Exhibit 10.1 to Form 8-K filed on December 19, 2012)	*
10.60	Third Amendment to Investors Rights Agreement dated as of December 11, 2012 (incorporated by reference to Exhibit 10.2 to Form 8-K filed on December 19, 2012)	*
10.61	Consent and Waiver of the Holders of 5% Senior Secured Convertible Promissory Note dated as of November 30, 2012 (incorporated by reference to Exhibit 10.3 to Form 8-K filed on December 19, 2012)	*
21.1	Subsidiaries of Registrant 3	*
		+
		+
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	+
	* Previously filed; incorporated herein by reference	
	+ Filed herewith	

 $_{\wedge}$ Portions of this exhibit have been redacted and filed separately with the SEC pursuant to a confidential treatment request.

Management contract or compensatory plan or arrangement.

#### **Signature**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

### TAMIR BIOTECHNOLOGY, INC.

Date: April 25, 2013 By:/s/ Jamie Sulley

Jamie Sulley President

(Principal Executive Officer)

Date: April 25, 2013 By:/s/ Joanne Barsa

Joanne Barsa

Chief Financial Officer and Secretary

(Principal Financial Officer and Chief Accounting Officer)

#### POWER OF ATTORNEY

The undersigned directors and officers of Tamir Biotechnology, Inc. do hereby constitute and appoint Jamie Sulley, and each of them, with full power of substitution and resubstitution, as their true and lawful attorneys and agents, to do any and all acts and things in our name and behalf in our capacities as directors and officers and to execute any and all instruments for us and in our names in the capacities indicated below, which said attorney and agent, may deem necessary or advisable to enable said corporation to comply with the Securities Exchange Act of 1934, as amended and any rules, regulations and requirements of the SEC, in connection with this Annual Report on Form 10-K, including specifically but without limitation, power and authority to sign for us or any of us in our names in the capacities indicated below, any and all amendments (including post-effective amendments) hereto, and we do hereby ratify and confirm all that said attorneys and agents, or either of them, shall do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1933, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u> <u>Title</u> <u>Date</u>

April 25, 2013

/s/ JAMIE SULLEY President and Director April 25, 2013 Jamie Sulley (Principal Executive Officer) /s/ JOANNE BARSA Chief Financial Officer and Secretary April 25, 2013 Joanne Barsa (Principal Financial and Accounting Officer) /s/ FRED KNOLL Director April 25, 2013 Fred Knoll /s/PATRICK OSTRONIC Director April 25, 2013 Patrick Ostronic /s/ DAVID SIDRANSKY Chairman of the Board April 25, 2013 David Sidransky /s/ JOHN P. BRANCACCIO Director April 25, 2013 John P. Brancaccio /s/ PAUL M. WEISS Director

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Paul M. Weiss, Ph.D

# Tamir Biotechnology, Inc.

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## Report of Independent Registered Public Accounting Firm

To the Board of Directors

Tamir Biotechnology, Inc.

San Diego, California

We have audited the balance sheet of Tamir Biotechnology, Inc. (the "Company"), as of July 31, 2011, and the related statement of operations, stockholders' deficiency and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of internal control over financial reporting. Our audit considered internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, based on our audit, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of July 31, 2011, and the results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred significant losses from operations and has an accumulated deficit of \$108,975,013 as of July 31, 2011. These conditions raise substantial doubt about the Company's ability to continue as a going concern. These financial statements do not include any adjustments that might result from such uncertainty.

/s/ Goldman Kurland and Mohidin LLP

Goldman Kurland and Mohidin LLP

Encino, California

April 25, 2013

#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors

Tamir Biotechnology, Inc.

We have audited the accompanying balance sheet of Tamir Biotechnology, Inc, as of July 31, 2010, and the related consolidated statements of operations, stockholders' deficit and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statement based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, and as well as evaluating the overall financial statement presentation. We believe that our audit provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Tamir Biotechnology Inc. as of July 31, 2010, and the results of their consolidated operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations, has a working capital deficit and negative cash flows from operating activities that raise substantial doubt about its ability to continue as a going concern. Management's plans in regards to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

## /s/ CohnReznick LLP

Roseland, New Jersey

October 29, 2010

**Balance Sheets** 

July 31, 2011 and 2010

Commitments and Contingencies

ASSETS	2011	2010
NODETO		
Current assets: Cash and equivalents Prepaid clinical trial expenses Prepaid expenses Restricted cash Total current assets	\$354,198 — 45,106 — 399,304	\$321,253 372,216 105,233 1,228,236 2,026,938
Property and equipment, net of accumulated depreciation of \$379,325 in 2011 and \$378,435 in 2010 Other assets Deferred financing costs	7,926 11,382 102,901	32,594 — 182,063
TOTAL ASSETS	\$521,513	\$2,241,595
LIABILITIES AND STOCKHOLDERS' DEFICIENCY		
Current liabilities: Accounts payable Accrued expenses Derivative liability Current portion of obligations under capital lease Deferred rent Total current liabilities	\$530,373 608,401 4,603,285 — 6,193 5,748,252	\$507,892 1,006,297 15,479,366 5,353 — 16,998,908
Other liabilities: Accounts payable, net of current portion Obligations under capital lease, net of current portion Accrued retirement benefits Deferred rent Convertible debt, less discount of \$1,341,553 (related party, \$572,534) Accrued interest, convertible debt (related party, \$85,880) Deferred revenue Total other liabilities	444,223 — 231,250 — 1,908,447 286,268 — 2,870,188	444,223 7,288 231,250 12,386 836,986 125,548 5,200,000 6,857,681
TOTAL LIABILITIES	8,618,440	23,856,589

Stockholders' deficiency:		
Preferred stock, \$0.001 par value. Authorized and unissued, 1,000,000 shares at		
July 31, 2011 and 2010	_	_
Common stock \$0.001 par value. Authorized 250,000,000 shares at July 31, 2011		
and 2010, issued and outstanding 49,823,880 and 47,313,880 shares at July 31, 2011	49,824	47,314
and 2010, respectively		
Additional paid in capital	100,828,262	101,456,909
Accumulated deficit	(108,975,013)	(123,119,217)
Total stockholders' deficiency	(8,096,927)	(21,614,994)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIENCY	\$521,513	\$2,241,595

See accompanying notes to financial statements.

Statements of Operations

Years Ended July 31, 2011 and 2010

	2011	2010
Revenues	\$5,200,000	\$18,750
Operating expenses: Research and development	857,722	517,870
General and administrative	(244,191)	*
Total operating expenses	613,531	2,221,367
Income (Loss) from operations	4,586,469	(2,202,617)
Investment income Interest and other income (expense):	250	1,132
Related parties, net	(48,216)	
Debt discount and fair value adjustment - Derivative Security Other	9,804,620 (197,979)	
Income (Loss) before state tax expenses (benefit)	14,145,144	(14,833,614)
State tax expenses (benefit)	940	(646,649 )
Net Income (Loss)	\$14,144,204	\$(14,186,965)
Income (Loss) per Basic and Diluted Common Shares:		
Basic	\$0.29	\$(0.30)
Diluted	\$0.05	\$(0.30)
Weighted Average Number of Shares Outstanding:		
Basic	48,109,962	
Diluted	93,575,337	47,313,000

See accompanying notes to financial statements.

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Statement of Stockholders' Deficiency

For the Years Ended July 31, 2011 and 2010

	Common Stoc Number of Shares	k Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficiency	
Balance at July 31, 2009	47,313,880	\$47,314	\$101,734,572	\$(108,932,252	) \$(7,150,366	)
Share-based compensation expense	_		333,422	_	333,422	
Derivative liability	_	_	(611,085	) —	(611,085	)
Net loss		_	<u> </u>	(14,186,965	) (14,186,965	)
Balance at July 31, 2010	47,313,880	47,314	101,456,909	(123,119,217	) (21,614,994	)
Common stock sold	2,500,000	2,500	497,500	_	500,000	
Stock option exercise	10,000	10	2,590	_	2,600	
Share-based compensation expense	_		(1,128,737	) —	(1,128,737	)
Net income	_	_	_	14,144,204	14,144,204	
Balance at July 31, 2011	49,823,880	\$49,824	\$100,828,262	\$(108,975,013	) \$(8,096,927	)

See accompanying notes to financial statements.

Statements of Cash Flows

For the Years Ended July 31, 2011 and 2010

	2011	2010
Cash Flows from Operating Activities:		
Net Income (loss)	\$14,144,204	\$(14,186,965)
Adjustments to reconcile net income (loss) to net		
cash (used in) operating activities:		
Depreciation and amortization	24,668	78,172
Share-based compensation expense	(1,128,737)	333,422
Decrease in deferred rent	(6,193	(271,748)
Amortization of debt discount	1,071,461	836,986
Fair value of derivative liability	(10,876,081)	11,618,281
Amortization of deferred financing costs	82,189	44,705
Changes in assets and liabilities:		
Decrease (increase) in prepaid expenses and	400.061	(400.055
other assets	420,961	(422,955)
Decrease (increase) in restricted cash	1,228,236	(961,956)
Increase in accounts payable	22,481	100,619
Decrease in accrued retirement benefits	_	(188,692)
Increase (decrease) in accrued expenses	(237,176	
Decrease in deferred revenue	(5,200,000	•
Net Cash Used in Operating Activities	(453,987	
Cash Flows from Investing Activities:		
Capital expenditures	_	(2,748)
Net Cash Used in Investing Activities	_	(2,748)
Cash Flows from Financing Activities:		
Increase in deferred financing costs	(3,027	, , ,
Payment of capital lease obligation	(12,641	(4,299)
Proceeds from issuance of common stock, net	500,000	_
Proceeds from exercise of stock options and warrants, net	2,600	
Proceeds from issuance of convertible debentures, related party	_	1,000,000
Proceeds from issuance of convertible debentures, unrelated party	_	2,250,000
Net Cash Provided by Financing Activities	486,932	3,018,933
Not increase in each and aguitalents	22.045	102.050
Net increase in cash and equivalents	32,945	192,059
Cash and equivalents at beginning of year	321,253	129,194
Cash and equivalents at end of year	\$354,198	\$321,253

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Supplemental Disclosure of Cash Flow Information

Cash paid for interest \$3,286 \$6,609 Cash paid for taxes \$940 \$—

Non-cash Transactions

Derivative liability – warrant reclassification \$— \$611,085

See accompanying notes to financial statements.

Tamir Biotechnology, Inc.

Notes to Financial Statements

Years ended July 31, 2011 and 2010

#### NOTE 1 - Business Description

Tamir Biotechnology, Inc. (formerly known as Alfacell Corporation) ("Tamir", "Company", "we", "us", "our", "our company" a Delaware corporation incorporated on August 24, 1981. We are a biopharmaceutical company primarily engaged in the discovery, development, and licensing of a new class of antiviral therapeutic drugs for the treatment of pathological conditions. Our proprietary drug discovery and development program consists of novel therapeutics which are being developed from amphibian ribonucleases (RNases). Since 2011, Tamir's focus has been its antiviral therapeutic drug development strategy and plan.

The Company is engaged in the research, development, licensing and commercialization of drugs for the treatment of various forms life threatening diseases. As of July 31, 2011, the Company is pursuing various available strategic alternatives to raise additional funds. The Company plans to continue the further development of its drug product candidates, which requires substantial capital for research, product development, and market development activities. The Company has not yet initiated marketing of a commercial drug product. Future product development will require clinical testing, regulatory approval, and substantial additional investment prior to commercialization. The future success of the Company is dependent on its ability to make progress in the development of its drug product candidates and, ultimately, upon its ability to attain future profitable operations through the successful manufacturing and marketing of those drug product candidates. There can be no assurance that the Company will be able to obtain the necessary financing or regulatory approvals to be able to successfully develop, manufacture, and market its products, or attain successful future operations. Accordingly, the Company's future success is uncertain.

The Company is no longer a development stage enterprise as it has started generating revenue from licensing, resulting from its past and ongoing research and development activities. Management expects to generate such revenue, as well as revenue from product sales, on an ongoing basis.

In addition, uncertainty exists as to the Company's ability to protect its rights to patents and its proprietary information. There can also be no assurance that research and discoveries by others will not render some or all of the Company's technology or drug product candidates noncompetitive or obsolete. Nor can there be any assurance that unforeseen problems will not develop with the Company's technologies or applications, or that the Company will be able to address successfully technological challenges it encounters in its research and development programs. While the Company maintains insurance to cover the use of its drug product candidates in clinical trials, it does not maintain insurance covering the sale of its products nor is there any assurance that it will be able to obtain or maintain such insurance on acceptable terms or with adequate coverage against potential liabilities.

#### NOTE 2 - Summary of Significant Accounting Policies

Going concern

The Company has suffered losses from operations and, without additional capital, currently lacks liquidity to meet its current obligations. The Company had net income of \$14,144,204 and net loss of \$14,186,965, in fiscal 2011 and 2010, respectively. As of July 31, 2011, the Company had a negative working capital of \$5,348,948 and an accumulated deficit of \$108,975,013. Unless additional financing is obtained, the Company may not be able to continue as a going concern. Since July 31, 2010, the Company raised a net of \$1,562,600 through the issuance of common stock, convertible debentures, stock options and warrants. The Company is seeking additional capital to continue its operations. However, due to the current economic environment and the Company's current financial condition, we cannot assure current and future stockholders there will be adequate capital available when needed and on acceptable terms.

The financial statements were prepared on a going concern basis which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of asset carrying amounts or the amount and classification of liabilities that might result if the Company is unable to continue as a going concern.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles ("U.S. GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expense during the reporting period. Actual results could differ from those estimates.

#### Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. The carrying value of these investments approximates their fair market value due to their short maturity and liquidity. The Company maintains cash deposits with banks that at times exceed applicable insurance limits.

#### Property and Equipment

Property and equipment is recorded at cost and is depreciated using the straight-line method over the estimated useful lives of the respective assets. Maintenance and repairs that do not extend the life of assets are expensed when incurred. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in operations for the period in which the transaction takes place.

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted cash flows expected to be generated by the asset. If the carrying amount exceeds its estimated future cash flows, an impairment charge is recognized in the amount by which the carrying amount exceeds the fair value of the asset.

#### Derivative Instrument Liability

The Company accounts for derivative instruments in accordance with ASC 815, which establishes accounting and reporting standards for derivative instruments and hedging activities, including certain derivative instruments embedded in other financial instruments or contracts and requires recognition of all derivatives on the balance sheet at fair value, regardless of the hedging relationship designation. Accounting for changes in the fair value of the derivative instruments depends on whether the derivatives qualify as hedge relationships and the types of relationships designated are based on the exposures hedged.

Accounting For Warrants Issued With Convertible Debt

The Company accounts for the intrinsic value of beneficial conversion rights arising from the issuance of convertible debt instruments with non-detachable conversion rights that are in-the-money at the commitment date pursuant to the consensuses of ASC 470-20 "Debt: Debt With Conversion and Other Options". Such value is allocated to additional paid—in capital and the resulting debt discount is charged to interest expense over the terms of the notes payable. Such value is determined after first allocating an appropriate portion of the proceeds received to warrants or any other detachable instruments included in the exchange.

Fair Value Measurements

The Company adopted ASC 820, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. ASC 820 applies to reported balances that are required or permitted to be measured at fair value under existing accounting pronouncements; accordingly, the standard does not require any new fair value measurements of reported balances.

ASC 820 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity's own assumptions about market participant assumptions (unobservable inputs classified within Level 3 of the hierarchy).

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access.

Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals.

Level 3 inputs are unobservable inputs for the asset or liability, which is typically based on an entity's own assumptions, as there is little, if any, related market activity.

In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Management provides valuation allowances against the deferred tax assets for amounts which are not considered "more likely than not" to be realized.

Revenue Recognition

The Company recognizes revenue in accordance with SEC Staff Accounting Bulletin ("SAB") No. 104, "Revenue Recognition" issued by the staff of the SEC. Under SAB No. 104, revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred and/or services have been rendered, the sales price is fixed or determinable, and collectability is reasonably assured.

The Company enters into marketing and distribution agreements, which contain multiple deliverables. Under the provisions of ASC 605, "Revenue Recognition - Multiple Deliverable Revenue Arrangements", the Company

evaluates whether these deliverables constitute separate units of accounting to which total arrangement consideration is allocated. A deliverable qualifies as a separate unit of accounting when the item delivered to the customer has standalone value, there is objective and reliable evidence of fair value of items that have not been delivered to the customer, and, if there is a general right of return for the items delivered to the customer, delivery or performance of the undelivered items is considered probable and substantially in the control of the Company. Arrangement consideration is allocated to units of accounting on a relative fair-value basis or the residual method if the Company is unable to determine the fair value of all deliverables in the arrangement. Consideration allocated to a unit of accounting is limited to the amount that is not contingent upon future performance by the Company. Upon determination of separate units of accounting and allocated consideration, the general criteria for revenue recognition are applied to each unit of accounting. Up-front nonrefundable fee received by the Company for substantive milestones are recognized upon achievement of the milestones. Any amounts receive prior to satisfying our revenue recognition criteria are recorded as deferred in the accompanying balance sheets.

In July 2007 the Company entered into an agreement with US Pharmacia Spolka Z.O.O. ("USP") to market, sell and distribute ONCONASE® in Poland and other countries in Eastern Europe. The Company received a \$0.1 million upfront nonrefundable fee in July 2007 and is entitled to receive future additional fees, milestone payments and royalties. USP is responsible for all commercial costs in the territory. The Company has agreed to provide or arrange for contract manufacture of a commercial supply of ONCONASE® upon receipt of marketing approval in the territory. The up-front nonrefundable fee received by the Company will be recognized ratably as revenue once the general criteria for revenue recognition has been met for the unit of accounting to which the fee has been allocated.

In January 2008, the Company entered into a marketing and distribution agreement with BL&H Co. Ltd. ("BL&H") for the commercialization of ONCONASE® in Korea, Taiwan and Hong Kong. Under the agreement, the Company received a \$0.1 million up-front fee and are eligible to receive additional cash milestones and 50% of net sales in the territory. The Company will be responsible for the manufacture and supply of ONCONASE® to BL&H, while BL&H will be responsible for all activities and costs related to regulatory filings and commercial activities in the territory.

In January 2008, the Company entered into a U.S. License Agreement for ONCONASE® with Par Pharmaceutical, Inc. ("Par"). Under the terms of the License Agreement, Strativa Pharmaceuticals ("Strativa"), the proprietary products division of Par, received exclusive marketing, sales and distribution rights to ONCONASE® for the treatment of cancer in the United States ("U.S.") and its territories. The Company retained all rights and obligations for product manufacturing, clinical development and obtaining regulatory approvals, as well as all rights for those non-U.S. jurisdictions in which the Company has not currently granted any such rights or obligations to third parties. The Company received a nonrefundable cash payment of \$5 million upon the signing of the License Agreement and would have been entitled to additional development and sales milestone payments and double-digit royalties on net sales of ONCONASE®.

On September 8, 2009, the Company and Par entered into a Termination and Mutual Release Agreement (the "Termination Agreement") pursuant to which the Company's License Agreement and Supply Agreement with Par were terminated. The License Agreement was terminated and all rights under the license granted to Par revert back to the Company under the Termination Agreement. Under the Supply Agreement, the Company had agreed to supply all of Par's requirements for ONCONASE. Pursuant to the Termination Agreement, Par will be entitled to a royalty of 2% of net sales of ONCONASE. or any other ranpirnase product developed by the Company for use in the treatment of cancer in the U.S. and its territories commencing with the first sale of such product and terminating upon the later to occur of the 12th anniversary of the first sale and the date of expiration of the last valid claim of a pending application or issued patent owned or controlled by the Company with respect to such product.

The Company has evaluated both the License Agreement and the Termination Agreement and has determined that the Company is obligated to provide royalty payments in the event the Company has net sales in the field of cancer. As such, the Company had not recognized into income any of the \$5 million upfront payment received under the License Agreement. In February 2011, we decided to suspend the Phase II trial of ONCONASE® in combination with carboplatinum regimens in patients suffering from non-small cell lung cancer who have reached maximum progression after receiving two cycles of Alimta plus Carboplatin. Given our limited resources and based upon previously reported positive *in vitro* antiviral results, we shifted our focus to the completion of *in vivo* studies for Dengue Fever, Yellow Fever, CMV, and HPV. At this point we terminated any further development of our compounds in the cancer field. Therefore, as of February 2011, there was nothing left to do to earn the non-refundable deposit and the Company has taken the \$5 million as income.

Research and Development

Research and development costs are expensed as incurred. These costs include, among other things, consulting fees and costs related to the conduct of human clinical trials. The Company also allocates indirect costs, consisting primarily of operational costs for administering research and development activities, to research and development expenses.

Share-Based Compensation

The Company accounts for its share-based compensation in accordance with the provisions of ASC 718, which establishes accounting for equity instruments exchanged for employee services and ASC 505-50, which establishes accounting for equity-based payments to non-employees. Under the provisions of ASC 718, share-based compensation is measured at the grant date, based upon the fair value of the award, and is recognized as an expense over the option holders' requisite service period (generally the vesting period of the equity grant). The Company is required to record compensation cost for all share-based payments granted to employees based upon the grant date fair value, estimated in accordance with the provisions of ASC 718. Under the provisions of ASC 505-50, measurement of compensation cost related to common shares issued to non-employees for services is based on the value of the services provided or the fair value of the shares issued. The measurement of non-employee stock-based compensation is subject to periodic adjustment as the underlying equity instrument vests.

The fair value of the stock options at the grant date was estimated using the Black-Scholes option pricing mode. The risk-free interest rate for periods approximating the expected life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The expected stock price volatility is based on historical volatility of the Company's stock price. For post July 31, 2005 grants, the expected term until exercise is derived using the "simplified" method as allowed under the provisions of the SEC's SAB No. 110, "Disclosures about Fair Value of Financial Instruments" and represents the period of time that options granted are expected to be outstanding.

Leases

With respect to our operating leases, the Company applies the provisions of the Financial Accounting Standards Board ("FASB") "Accounting for Leases", recognizing rent expense on a straight-line basis over the lease term due to escalating lease payments and landlord incentives.

**Contingencies** 

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, and penalties and other sources are recorded when it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated. Recoveries from other parties are recorded when realized.

Recently Issued Accounting Pronouncements

In June 2011, FASB issued Accounting Standards Update ("ASU") 2011-05, "Comprehensive Income (Topic 220): Presentation of Comprehensive Income," which is effective for annual reporting periods beginning after December 15, 2011. ASU 2011-05 will become effective for the Company on January 1, 2012. This guidance eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. In addition, items of other comprehensive income that are reclassified to profit or loss are required to be presented separately on the face of the financial statements. This guidance is intended to increase the prominence of other comprehensive income in financial statements by requiring that such amounts be presented either in a single continuous statement of income and comprehensive income or separately in consecutive statements of income and comprehensive income. The adoption of ASU 2011-05 is not expected to have a material impact on our financial position or results of operations.

In May 2011, the FASB issued ASU 2011-04, "Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs," which is effective for

annual reporting periods beginning after December 15, 2011. This guidance amends certain accounting and disclosure requirements related to fair value measurements. Additional disclosure requirements in the update include: (1) for Level 3 fair value measurements, quantitative information about unobservable inputs used, a description of the valuation processes used by the entity, and a qualitative discussion about the sensitivity of the measurements to changes in the unobservable inputs; (2) for an entity's use of a nonfinancial asset that is different from the asset's highest and best use, the reason for the difference; (3) for financial instruments not measured at fair value but for which disclosure of fair value is required, the fair value hierarchy level in which the fair value measurements were determined; and (4) the disclosure of all transfers between Level 1 and Level 2 of the fair value hierarchy. ASU 2011-04 will become effective for the Company on January 1, 2012. The Company does not expect that the guidance effective in future periods will have a material impact on its financial statements.

In April 2011, the FASB issued ASU 2011-02, "Receivables (Topic 310): A Creditor's Determination of Whether a Restructuring is a Troubled Debt Restructuring." This amendment explains which modifications constitute troubled debt restructurings ("TDR"). Under the new guidance, the definition of a troubled debt restructuring remains essentially unchanged, and for a loan modification to be considered a TDR, certain basic criteria must still be met. For public companies, the new guidance is effective for interim and annual periods beginning on or after June 15, 2011, and applies retrospectively to restructuring occurring on or after the beginning of the fiscal year of adoption. The Company does not expect that the guidance effective in future periods will have a material impact on our financial statements.

In January 2010, the FASB issued an amendment to ASC 820, "Fair Value Measurements and Disclosure," to require reporting entities to separately disclose the amounts and business rationale for significant transfers in and out of Level 1 and Level 2 fair value measurements and separately present information regarding purchase, sale, issuance, and settlement of Level 3 fair value measures on a gross basis. This standard is effective for interim and annual reporting periods beginning after December 15, 2009 with the exception of disclosures regarding the purchase, sale, issuance, and settlement of Level 3 fair value measures which are effective for fiscal years beginning after December 15, 2010. The adoption of this standard is not expected to have a significant impact on the Company's financial statements.

The Company has implemented all new accounting pronouncements that are in effect. These pronouncements did not have any material impact on the financial statements unless otherwise disclosed, and the Company does not believe that there are any other new accounting pronouncements that have been issued that might have a material impact on its financial position or results of operations.

#### NOTE 3 - Restricted Cash

Restricted cash was an escrow account held by a bank which can only disburse funds to satisfy obligations of the Company owed to clinical research organizations, hospitals, doctors and other vendors and service providers associated with the clinical trials which the Company intends to conduct for its ONCONASE® product. The escrow agreement governing the account shall terminate on the earlier of the date that all funds have been disbursed from the escrow account or April 19, 2011, at which time any remaining funds will be disbursed to the Company. The escrow account was terminated at April 20, 2011.

#### NOTE 4 - Net Income (Loss) Per Common Share

The following table sets forth the computation of basic and diluted net income (loss) per common share:

	Year Ended July 31,		
	2011	2010	
Numerator:			
Net income (loss)	\$14,144,204	\$(14,186,965	5)
Denominator:			
Weighted average number of common shares outstanding	48,109,962	47,313,000	
Income (loss) per common share - basic and diluted			
Basic	\$0.29	\$(0.30	)
Diluted	\$0.05	\$(0.30	)
Potentially dilutive securities:			

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Warrants	45,833,328	49,784,000
Convertible notes (principal & interest)	23,575,111	22,503,651
Stock options	3,854,867	3,535,467
Total potentially dilutive securities	73,263,306	75,823,118

As the Company has incurred a net loss for fiscal 2010, basic and diluted per common share amounts are the same, since the inclusion of all potentially dilutive securities would be anti-dilutive.

## NOTE 5 - Property and Equipment

Property and equipment, at cost, consists of the following at July 31:

	2011	2010
Laboratory equipment	\$276,202	\$276,202
Office equipment	111,049	111,049
Leasehold improvements		23,778
Less accumulated depreciation	(379,325)	(378,435)
Property and equipment, net	\$7,926	\$32,594

Depreciation for fiscal 2011 and 2010 was \$24,668 and \$78,172, respectively.

#### NOTE 6 - Convertible Notes and Warrants

On October 19, 2009, the Company completed a sale of 65 units (the "Units") in a private placement (the "Offering") to certain investors pursuant to a securities purchase agreement (the "Securities Purchase Agreement"). Each Unit consists of (i) \$50,000 principal amount of 5% Senior Secured Convertible Promissory Notes (collectively, the "Notes") convertible into shares of the Company's common stock, par value \$.001 per share ("Common Stock"), (ii) Series A Common Stock Purchase Warrants (the "Series A Warrants") to purchase in the aggregate that number of shares of Common Stock initially issuable upon conversion of the aggregate amount of Notes issued as part of the Unit, at an exercise price of \$0.15 per share with a three year term and (iii) Series B Common Stock Purchase Warrants (the "Series B Warrants", together with the Series A Warrants, the "Warrants") to purchase in the aggregate that number of shares of Common Stock initially issuable upon conversion of the aggregate amount of Notes issued as part of the Unit, at an exercise price of \$0.25 per share with a five year term. The closing of the Offering occurred on October 19, 2009 (the "Closing") and the Company received an aggregate of \$3,250,000 in gross proceeds.

The Notes mature on the earlier of (i) October 19, 2012; (ii) the closing of a public or private offering of the Company's debt or equity securities subsequent to the date of issuance resulting in gross proceeds of at least \$8,125,000 other than a transaction involving a stockholder who holds 5% or more of the Company's outstanding capital stock as of the date of issuance; or (iii) on the demand of the holder of the Note upon the Company's consummation of a merger, sale of substantially all of its assets, or the acquisition by any entity, person or group of 50% or more of the voting power of the Company. Interest accrues on the principal amount outstanding under the Notes at 5% per annum, and is due upon maturity. Upon an event of default under the Notes, the interest rate shall increase to 7%. On April 27, 2010, the stockholders approved an amendment to the certificate of incorporation increasing the number of authorized shares of capital stock of the Company to cover the conversion of the Notes and

exercise of the Warrants. The amendment was filed on the same date. The Notes are convertible into Common Stock at the option of the holder of the Note at a price of \$0.15 per share at any time prior to the date on which the Company makes payment in full of all amounts outstanding under the Note. The Notes are not prepayable for a period of one year following the issuance thereof. The Notes are secured by a senior security interest and lien on all of the Company's right, title and interest to all of the assets owned by the Company as of the Closing or thereafter acquired pursuant to the terms of a security agreement (the "Security Agreement") entered into by the Company with each of the investors. The Warrants are exercisable immediately following the Closing.

In connection with the Offering, the Company entered into an investor rights agreement (the "Investor Rights Agreement") with each of the investors. The Investor Rights Agreement provides that the Company will file a "resale" registration statement (the "Initial Registration Statement") covering all of the shares issuable upon conversion of the Notes (the "Note Shares") and the shares issuable upon exercise of the Warrants (the "Warrant Shares", together with the Note Shares, the "Securities"), up to the maximum number of shares able to be registered pursuant to applicable Securities and Exchange Commission ("SEC") regulations, within 120 days of the Closing (the "Filing Deadline"). On February 26, 2010, the Company and the investors amended the Investor Rights Agreement (the "Rights Agreement Amendment") to extend the Filing Deadline to May 1, 2010, which Rights Agreement Amendment was filed with the Form 8-K filed by the Company on March 4, 2010. In accordance with the Investor Rights Agreement, on April 30, 2010, the Company filed with the SEC a "resale" registration statement on Form S-1. If any Securities are unable to be included on the Initial Registration Statement, the Company has agreed to file subsequent registration statements until all the Securities have been registered. Under the terms of the Investor Rights Agreement, the Company is obligated to maintain the effectiveness of the "resale" registration statement until all securities therein are sold or otherwise may be sold by non-affiliates pursuant to Rule 144, without restrictions. A cash penalty at 1% per month will be triggered in the event the Company fails to file or obtain the effectiveness of a registration statement prior to the deadlines set forth in the Investor Rights Agreement, which deadlines were extended by the Rights Agreement Amendment, or if the Company ceases to be current in filing its periodic reports with the SEC. The aggregate penalty accrued with respect to each investor may not exceed 6% of the original purchase price paid by that investor, or 12% if the only effectiveness failure is the Company's failure to be current in its periodic reports with the SEC.

On July 31, 2010, the Company entered into a second amendment to the Investor Rights Agreement with the investors, pursuant to which the investors waived their right to receive penalties in respect of all matters occurring prior to the date of the second amendment, which included the Company's failure to obtain the effectiveness of a registration statement within the deadlines set forth in the Investor Rights Agreement. In addition, the second amendment postponed the investors' right to require the Company to file a "resale" registration statement covering all of the shares issuable upon conversion of the Senior Secured Notes and the shares issuable upon exercise of the Warrants until after the Company's next financing which yields gross proceeds of at least \$3,250,000. In the event of such a financing, and following a written demand made by the holders of the majority of the registerable securities, the Company must file, within 90 days of its receipt of the demand notice, either a new "resale" registration statement registered the shares or amend the registration statement the Company filed on April 30, 2010.

In connection with the Offering, the Company also entered into an escrow agreement (the "Escrow Agreement") whereby certain investors placed \$1,600,000 of the proceeds paid for their Units in an escrow account pursuant to the terms of the Securities Purchase Agreement. Such amounts can be disbursed from the escrow account only to satisfy obligations of the Company owed to clinical research organizations, hospitals, doctors and other vendors and service providers associated with the clinical trials which the Company intends to conduct for its ONCONASE® product. The Escrow Agreement shall terminate on the earlier of the date that all funds have been disbursed from the escrow account and April 19, 2011, at which time any remaining funds will be disbursed to the Company.

Charles Muniz, the Company's President, Chief Executive Officer and Chief Financial Officer, subscribed for 20 Units; certain trusts and individuals related to James O. McCash, a beneficial owner of more than five percent of the Company's voting securities, subscribed for an aggregate of 20 Units; Europa International Inc., a beneficial owner of

more than five percent of the Company's voting securities, subscribed for 15 Units; and Unilab LP, an affiliate of US Pharmacia, an affiliate of the Company's distributor for ONCONASE® in Eastern Europe and a current stockholder, subscribed for 10 units. These investors are party to the Securities Purchase Agreement, the Investor Rights Agreement, the Security Agreement and the Escrow Agreement. The Company's entry into an employment agreement with Mr. Muniz upon terms reasonably acceptable to the investors in the Offering was a condition to the Closing.

The Company concluded that it should account for the warrants and conversion options embedded in the Notes in accordance with ASC Topic "Derivatives and Hedging". Accordingly, the Company determined that the warrants and the conversion options embedded in the Notes should be accounted for as free standing derivatives that will be measured at fair value and classified as liabilities at the closing of the Offering. Each subsequent reporting period, the Company will mark to market the warrants and conversion feature of Notes with any change in fair value recorded through the statement of operations. This accounting treatment is due to the fact that the settlement terms of the warrants and conversion feature of the Notes do not allow them to qualify for equity presentation due to down-round protection. Accordingly, on October 19, 2009, in connection with the closing of the Offering, the convertible feature of the Notes were recorded as a derivative liability of approximately \$6.1 million and the Series A and Series B warrants were recorded as a derivative liability of approximately \$6.1 million each, respectively.

At the closing for the Offering, the fair value of the conversion feature, approximately \$6.1 million, exceeded the proceeds of \$3.25 million. The difference of approximately \$2.9 million was charged to expense as the change in the fair market value of the conversion liability. Accordingly, the Company recorded an initial discount of \$3.25 million equal to the face value of the Notes, which will be amortized over the three-year term, using the straight-line method.

At July 31, 2011, the Company accounted for the conversion feature using the fair value method, with the resultant gain recognition recorded in the statement of operations. At July 31, 2011, the fair value of the conversion feature liability was \$1.3 million. The fair value of the conversion feature was \$6.1 million at the closing for the Offering and \$5.2 million at July 31, 2010. The conversion feature was valued at July 31, 2011 and July 31, 2010 using the Black-Scholes valuation model and the following assumptions:

	July 31, 2011	July 31, 2010
Volatility Risk-free interest rate Remaining contractual life (years)	0.09 %	153.71% 0.55 % 2.22

At the Closing, the Company recorded the Series A and Series B warrants as liabilities at their fair values of \$6.1 million each, based upon the Black-Scholes valuation model. The warrants have been accounted for using mark-to-market accounting and charged to the statement of operations in a manner similar to the conversion feature at each reporting date.

At July 31, 2011, the Company accounted for the warrant liabilities using the fair value method, with the resultant gain recognition recorded in the statement of operations. At July 31, 2011, the fair value of the Series A and Series B warrant liabilities were approximately \$1.3 million and \$2.0 million, respectively. The fair value of the Series A warrant was \$6.1 million at the closing for the Offering and \$5.2 million at July 31, 2010. The fair value of the Series B warrant was \$6.1 million at the closing for the Offering and \$5.1 million at July 31, 2010.

The Series A and Series B warrant liabilities were valued at July 31, 2011 and July 31, 2010 using the Black-Scholes valuation model and the following assumptions:

Series A Warrants Series B Warrants

## July 31, 2011 July 31, 2010 July 31, 2011 July 31, 2010

Volatility	156.53%	153.71%	174.80%	123.44%
Risk-free interest rate	0.09%	0.55%	0.48%	1.22%
Remaining contractual life (years)	1.22	2.22	3.22	4.22

## NOTE 7 - Stockholders' Deficiency

On April 27, 2010, at the Company's annual stockholders' meeting, the Company's stockholders approved an amendment to the Company's Certificate of Incorporation, as amended, to increase the number of shares of common stock authorized from 100,000,000 to 250,000,000.

During fiscal 2010, the Company issued 11,667 stock options to its former member of the Board of Directors with an exercise price of \$0.34 per share and a five-year exercise term. The grant date fair market value of these options in the amount of \$2,812 was recognized as an expense for the fiscal year ended July 31, 2010.

During fiscal 2010, the Company issued 430,000 stock options to the independent members of its Board of Directors with an exercise price of \$0.26 per share and a 68 month exercise term. The aggregate grant date fair market value of these options in the amount of \$85,570 is being amortized over the eight-month vesting period. The Company recognized an aggregate compensation expense of \$31,447 for the fiscal year ended July 31, 2010.

During fiscal 2010 the Company evaluated the classification of all non-employee share commitments issued outside of the plans which existed prior to the Offering (the "Prior Non-Employee Commitments"). As a result, at October 19, 2009, the Company reclassified \$747,235 from equity to liability for all Prior Non-Employee Commitments and has included this amount as a part of derivative liability. The Company marked to market the Prior Non-Employee Commitments at April 27, 2010 and recorded a gain of \$611,085 for the change in fair value from October 19, 2009 to April 27, 2010. On April 27, 2010, the Company's stockholders approved an amendment to the Company's certificate of incorporation increasing the amount of authorized shares to cover all existing share commitments therefore, the marked-to-market liabilities for Prior Non-Employee Commitments were reclassified to equity in the amount of \$136,150.

During fiscal 2011, the Company issued 430,000 stock options to the independent members of its Board of Directors with an exercise price of \$0.12 per share and a 67 month exercise term. The aggregate grant date fair market value of these options of \$40,850 is being amortized over the seven-month vesting period. The Company recognized compensation expense of \$11,438 for the fiscal year ended July 31, 2011. The Company issued 90,000 stock options to a non-employee consultant for services rendered. The options vested immediately, have an exercise price of \$0.34 per share and a five-year exercise term. The aggregate grant date fair market value of these options, \$25,380, was recognized as an expense by the Company during the fiscal year ended July 31, 2011. During the fiscal year ended July 31, 2011, the Company issued 10,000 shares of its common stock upon the exercise of stock options by an employee at per share exercise prices of \$0.26. The Company realized aggregate gross proceeds of \$2,600 from this exercise.

In April 2011, the Company completed the sale of 2,500,000 shares of its common stock and the issuance of warrants to purchase 2,500,000 common shares pursuant to an agreement with Unilab LP. The company received proceeds of \$500,000. The warrants have a 5-year term and a purchase price of \$0.50 per share.

As of April 2011, the fair value of these warrants was \$0.2 million. The warrants were valued using the Black-Scholes valuation model and the following assumptions:

April 2011

Volatility 143.73% Risk-free interest rate 2.07 % Remaining contractual life (years) 5.00

These warrants were plain vanilla warrants with standard antidilutive provisions, as such, they were classified as equity instruments and recorded as a change and credit to additional paid-in capital.

## NOTE 8 - Common Stock Warrants

The following table summarizes the activity of common stock warrants issued in connection with the private placements and conversion of notes payable completed in fiscal years 2010 and 2011:

Outstanding at July 31, 2009 Expired	Warrants 8,495,650 (2,044,978)	Exercise Price 1.00 - 2.88 1.00	Expiration 9/14/09 to 7/17/11 9/14/09 to 5/6/10
Issued to related parties in connection with conversion of notes payable	13,333,332	0.15 - 0.25	10/19/12 to 10/19/14
Issued to unrelated parties in connection with conversion of notes payable	29,999,996	0.15 - 0.25	10/19/12 to 10/19/14
Outstanding at July 31, 2010	49,784,000	\$0.15 - \$2.88	7/17/11 to 10/19/14
Expired	(6,450,672)	2.88	07/17/2011
Issued to unrelated parties	2,500,000	0.50	04/07/2016
Outstanding at July 31, 2011	45,833,328	\$0.15-0.50	10/19/12 to 4/7/16
Exercisable at July 31, 2011	45,833,328	\$0.15-0.50	10/19/12 to 4/7/16

#### NOTE 9 - Stock Options

#### 2004 Stock Incentive Plan

The Company's stockholders approved the 2004 Stock Incentive Plan (the "2004 Plan") for the issuance of up to 8,500,000 shares, which provides that common stock and stock options may be granted to employees, directors and consultants. The 2004 Plan provides for the granting of stock options, stock appreciation rights, restricted shares, or other share based awards to eligible employees and directors, as defined in the 2004 Plan. Options granted under the 2004 Plan will have an exercise price equal to the market value of the Company's common stock on the date of the grant. The term, vesting period and time and method of exercise of options granted under the 2004 Plan are fixed by the Board of Directors or a committee thereof.

### 1997 Stock Option Plan

The Company's stockholders approved the 1997 stock option plan for the issuance of options for up to 2,000,000 shares, which provides that options may be granted to employees, directors and consultants. Options are granted at market value on the date of the grant and generally are exercisable in 20% increments annually over five years starting one year after the date of grant and terminate five years from their initial exercise date. This plan expired in May 2007 except to the extent there are outstanding options.

#### 1993 Stock Option Plan

The Company's stockholders approved the 1993 stock option plan for the issuance of options for up to 3,000,000 shares, which provides that options may be granted to employees, directors and consultants. Options are granted at market value on the date of the grant and generally are exercisable in 20% increments annually over five years starting one year after the date of grant and terminate five years from their initial exercise date. This plan expired in November 2003 except to the extent there are outstanding options.

The fair value of the stock options at the grant date was estimated using the Black-Scholes valuation model and the following assumptions:

2011 2010

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Expected dividend yield	0	%	0	%
Risk-free interest rate	0.84		2.17	%
Expected volatility	138.07		120.6	3%
Expected term (years)	3.1 - 5.	0	4.66	
Weighted average fair value of options at grant date	\$0.13		\$0.25	
Weighted average fair value exercise price	\$0.16		\$0.30	

For post July 31, 2005 grants, the expected term until exercise is derived using the "simplified" method as allowed under the provisions of the SEC's SAB No. 110, "Disclosures about Fair Value of Financial Instruments" and represents the period of time that options granted are expected to be outstanding.

## **Option Activity**

The following table summarizes stock option activity for the period July 31, 2009 through July 31, 2011:

	Shares		Weighted Average Exercise Price	Weighted Average Remaining Contractual <u>Term</u>	Aggregate
	Available for	Options	Per Share		Intrinsic
	<u>Grant</u>	Outstanding			<u>Value</u>
Balance July 31, 2009	5,012,500	4,771,650	\$ 2.64		
Granted	(941,667)	941,667	0.30		
Cancelled/Expired	1,096,500	(2,169,850)	3.56		
Forfeited	8,000	(8,000)	1.29		
Balance July 31, 2010	5,175,333	3,535,467	1.45	6.03	\$ 25,000
Granted	(520,000)	(520,000)	0.16		
Cancelled/Expired	50,000	190,600	2.85		
Exercised	-	(10,000)	0.26		
Balance July 31, 2011	4,705,333	3,854,867	1.21	5.35	\$ 0
Exercisable at July 31, 2010		- 1,605,467	\$ 1.78	4.13	\$ 12,100
Exercisable at July 31, 2011		2,091,517	\$ 1.20	4.21	\$ 0

At July 31, 2011, the Company reversed a total of \$1,228,572 compensation expense related to 1,000,000 performance stock options issued in April 2008. The Company concluded that the performance condition was deemed improbable as of February 2011; therefore, the expense to-date was reversed in accordance to FASB ASC 718, "Compensation – Stock Compensation."

## NOTE 10 - Income Taxes

The Company accounts for income taxes under the provisions of ASC Accounting for Income Taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for all years in which the temporary differences are expected to reverse.

New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell a portion of its state tax loss carry forwards and state research and development credits in order to obtain state tax benefits. For the state fiscal year 2010 (July 1, 2009 to June 30, 2010), the Company had approximately \$723,000 of total available state tax benefit that was saleable. In February 2010, the Company received approximately \$647,000 from the sale of its total available state tax benefit, which was recognized as state tax benefit in the fiscal year ended July 31, 2010. For the state fiscal year 2009 (July 1, 2008 to June 30, 2009), the Company had approximately \$1,274,000 of total available state tax benefit that was saleable. On December 1, 2008, the Company received approximately \$1,140,000 from the sale of its total available state tax benefit, which was recognized as state tax benefit in the fiscal year ended July 31, 2009. For the state fiscal year 2011 (July 1, 2010 to June 30, 2011), the Company did not qualify to participate in the program.

At July 31, 2011 and 2010, the tax effects of temporary differences that give rise to the deferred tax assets are as follows:

Deferred tax assets:	2011	2010
Excess of book over tax depreciation and amortization	\$11,434	\$9,727
Stock options	2,689,271	2,724,202
Deferred revenue	_	2,080,000
Temporary differences	1,438,959	5,475,673
Federal and state net operating loss carry forwards	21,510,701	23,277,136 *
Research and experimentation credit carry forwards	2,372,658	2,329,646 *
Total gross deferred tax assets	28,023,023	35,896,384
Valuation allowance	(28,023,023)	(35,896,384)
Net deferred tax assets	\$—	<b>\$</b> —

<sup>\*</sup> Net of amount sold pursuant to New Jersey state tax legislation.

A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. The tax benefit assumed using the federal statutory tax rate of 34% has been reduced to the actual benefits reflected on the statements of operations due principally to the aforementioned valuation allowance.

At July 31, 2011, the Company has federal net operating loss carry forwards of approximately \$62,705,807 that expire in the years 2012 to 2030 and state net operating loss carry forwards of approximately \$2,119,188 that expire in years 2018 to 2019. Ultimate utilization/availability of such net operating losses and credits is dependent upon the Company's ability to generate taxable income in the future and may be significantly curtailed if a significant change in ownership occurs in accordance with the provisions of the Tax Reform Act of 1986.

The Company also has federal research and experimentation tax credit carryforwards of approximately \$2,232,000 that expire in the years 2011 to 2030 (approximately \$623,000 expires in the years 2011 to 2015) and state research and experimentation tax credits of approximately \$141,000 that expire in the years 2025 to 2026. Ultimate utilization/availability of such net operating losses and credits is dependent upon the Company's ability to generate taxable income in future periods and may be significantly curtailed if a significant change in ownership occurs in accordance with the provisions of the Tax Reform Act of 1986.

The Company files income tax returns in the U.S. federal jurisdiction and New Jersey. For federal income tax purposes, fiscal 2008 through 2011 tax years generally remain open for examination by the tax authorities under the normal three-year statute of limitations. For New Jersey tax purposes, fiscal 2007 through 2011 tax years generally

remain open for examination under a four-year statute of limitations.

A reconciliation of the income tax expense (benefit) computed at the federal statutory rate to the record in the financial statements for year-end July 31, 2011and 2010 is as follows:

	2011	2010
Federal credit at Statutory rate	34.0 %	(34.0)%
State tax, net of federal benefit	6.0 %	(6.0)%
Change in Fair Value of Derivatives	(76.9)%	78.3 %
Change in Valuation Allowance	36.9 %	(38.3)%
Benefit realized from sale of State NOL	_ %	(4.4)%
Total	%	(4.4)%

## NOTE 11 - Related Party Transactions

On October 19, 2009, Charles Muniz, the Company's President, Chief Executive Officer and Chief Financial Officer, was a party to the Securities Purchase Agreement, the Investor Rights Agreement, the Security Agreement and the Escrow Agreement. The Company's entered into an employment agreement with Mr. Muniz upon terms reasonably acceptable to the investors in the Offering was a condition to the Closing.

In December 2009, the Company engaged Champions Biotechnology, Inc. to provide certain services for approximately \$99,900. The Company's non-executive Chairman of the Board of Directors, Dr. David Sidransky, is also the chairman of the board of directors as well as a principal stockholder of Champions Biotechnology, Inc. As of July 31, 2010, the agreed amount was paid in full.

#### NOTE 12 - Commitments

**Employment and Retirement Agreements** 

On October 19, 2009, the Company entered into an Employment Agreement (the "Employment Agreement") with Mr. Muniz. Pursuant to the Employment Agreement, Mr. Muniz shall serve as the Company's President, Chief Executive Officer and Chief Financial Officer, Mr. Muniz was to receive an annual base salary of \$300,000 and is entitled to receive cash incentive compensation or annual stock option awards as determined by the Board or the Compensation Committee of the Board from time to time. In addition, Mr. Muniz is entitled to participate in any and all employee benefit plans established and maintained by the Company for executive officers of the Company. Pursuant to the Employment Agreement, Mr. Muniz received an option (the "Option"), granted under and in accordance with the Company's 2004 Stock Incentive Plan, to purchase an aggregate of 500,000 shares of Common Stock exercisable for ten years from the date the Option is granted. The Option shall vest in equal amounts on each of the first, second and third year anniversary of the grant so long as Mr. Muniz remains employed by the Company. The exercise price of the Option was equal to the fair market value of the Common Stock on the date of grant. The Employment Agreement continues in effect for two years following the date of the agreement and automatically renews for successive one-year periods, unless Mr. Muniz's employment is terminated by him or by the Company. In the event that Mr. Muniz's employment is terminated by the Company for any reason, then Mr. Muniz is entitled to receive his earned but unpaid base salary and incentive compensation, unpaid expense reimbursements, accrued but unused vacation and any vested benefits under any employee benefit plan of the Company. In the event that Mr. Muniz's employment is terminated by the Company without "cause" or by Mr. Muniz for "good reason" (as such terms are defined in the Employment Agreement), then in addition to the above mentioned payments and benefits, Mr. Muniz is entitled to receive an amount equal to his then current annual base salary, payable in equal installments over 12 months in accordance with the Company's payroll practice and all medical and health benefits for 18 months following the termination date. Mr. Muniz's Employment Agreement requires him to refrain from competing with the Company and from hiring our employees and soliciting our customers for a period of one year following the termination of his employment with the

Company for any reason.		
Company for any reason.		

Lease Commitments

In November 2007, the Company entered into a capital lease agreement for its building security system for the term of five years with a payment of \$635 per month. The lease agreement gave the Company the right to purchase the leased equipment at the end of the lease term for \$1.00 plus applicable taxes. The contract was closed in June 2011.

On September 28, 2010, the Company entered into an office lease agreement effective as of October 1, 2010 with Princeton Corporate Plaza, LLC for \$3,794 per month including expenses. The Company leased 2,046 square feet of office and laboratory space in the building located at 11 Deer Park Drive, Suite 204, in the township of South Brunswick in the County of Middlesex, State of New Jersey. The lease term ended on September 30, 2011.

There are no future minimum lease payments under non-cancelable operating leases (with initial or remaining terms in excess of one year) as of July 31, 2011.

Defined Contribution Retirement Plan (401(k) Plan)

Effective October 1, 1998, the Company adopted a 401(k) Savings Plan (the "Plan"). Qualified employees may participate by contributing to the Plan subject to certain Internal Revenue Service restrictions. Since the plan was amended in April 2009 the company did not matched any contribution to the plan.

## NOTE 13 - Contingencies

The Company has product liability insurance coverage for clinical trials in the U.S. and in other countries where it conducts its clinical trials. No product liability claims have been filed against the Company. If a claim arises and the Company is found liable in an amount that significantly exceeds the policy limits, it may have a material adverse effect upon the financial condition and results of operations of the Company.

#### NOTE 14 - Subsequent Events

On December 16, 2011, the Board determined that the employment of Charles Muniz, President, Chief Executive Officer and Chief Financial Officer of Tamir, would end.

On December 23, 2011, the Board of Directors (the "Board") of Tamir Biotechnology, Inc. ("Tamir") appointed Lawrence A. Kenyon as interim Chief Executive Officer and Chief Financial Officer of Tamir, effective immediately. Mr. Kenyon entered into a consulting agreement with the Company pursuant to which he received monthly salary of \$5,000.

On November 23, 2011, Tamir entered into a Memorandum of Understanding ("MOU"), with US Pharmacia, hereafter (USPI and/or affiliates), pursuant to which USPI, will be granted the exclusive marketing, sales, and distribution rights of ONCONASE® for use in Human Papillioma Virus (HPV) in the European Territory upon completion of full License payment. Territory includes Western and Eastern Europe. USPI was to pay Tamir the sum of \$1 million in installments provided Tamir achieves certain milestones. Under the MOU, on December 12, 2011, Tamir received an initial payment of \$405,000 and Tamir provided USPI with Proof of Concept ("POC") demonstrating successful drug formulation of ONCONASE® which will be used to treat genital and skin warts caused by the HPV and *in vivo* penetration of Onconase into the skin. Tamir provided this POC by March 31, 2011. USPI further agreed to make a \$95,000 milestone payment to Tamir, for the completion of a topical formulation and initiation of testing of ONCONASE® in the HPV Proof of Concept study. On June 13, 2012, Tamir received initial results from the independent laboratory performing the ongoing non-clinical proof-of-concept study of ONCONASE® as a potential HPV drug. Once other pre-clinical milestones are met USPI shall pay Tamir the balance of \$500,000 in installments.

The terms of the License Agreement shall be agreed upon by the parties as outlined in the MOU. Tamir will also be entitled to receive milestone payments based on the achievement of certain regulatory approvals and certain sales goals. In addition, Tamir will receive a royalty on net sales as well as a transfer price for product sold by Tamir to USPI.

Tamir will be responsible for making regulatory filings with and seeking marketing approval of ONCONASE® in the Territory and manufacturing and supplying ONCONASE® to USPI. USPI will be responsible for all commercial activities and related costs in the Territory.

On May 30, 2012, Tamir was served with a complaint filed by its current board member and former President and Chief Executive Officer, Charles Muniz, in the Superior Court of New Jersey, Middlesex County. In the complaint Mr. Muniz alleges that his employment with Tamir was wrongfully terminated and that such termination was in retaliation for his complaints to the Board. Mr. Muniz claims the Board failed to disclose material and significant information to investors and shareholders about ONCONASE® for HPV and that such failure to disclose such information constituted unlawful deception, misrepresentation, violation of the board's fiduciary responsibilities and fraudulent activity. Mr. Muniz is seeking unspecified damages. Tamir believes Mr. Muniz's allegations are without merit and intends to defend itself from his claims to the extent it has the resources to do so.

Although Mr. Muniz's complaint does not specify what information about ONCONASE® for HPV he alleges the Board failed to disclose, based upon communications the Board has received from Mr. Muniz, Tamir believes that Mr. Muniz is referring to his contention that passive transdermal delivery of large molecular weight molecules was not scientifically possible and that Tamir should not pursue the development of such a formulation of ONCONASE®. Although the preliminary test results discussed above need to be further evaluated through testing, Tamir believes that these preliminary test results demonstrate that Mr. Muniz's contention that passive transdermal delivery of large molecular weight molecules, specifically ONCONASE®, was scientifically impossible, is incorrect. As was explained to Mr. Muniz numerous times before he filed his lawsuit, the Board made a determination to pursue the development of several formulations of ONCONASE® that could achieve passive transdermal delivery, based upon reasonable scientific processes and the emergence of new powerful patented formulations that facilitate transdermal delivery of large molecular weight molecules that might make it possible to develop such a formulation for ONCONASE®. The Board's decision was also based upon the fact that Tamir had essentially no cash remaining, USPI was the company's only funding source and USPI was only willing to fund the development of such a formulation of ONCONASE®. During his tenure as Chief Executive Officer, Mr. Muniz was unable to secure a partner or investors willing to fund any formulation of ONCONASE® for the treatment of HPV other than those formulations that Tamir has pursued.

On October 18, 2012, by action of a majority of the holders (the "Required Holders") of the Tamir Biotechnology, Inc. 5% Senior Secured Convertible Promissory Notes (the "Notes"), the maturity date of the Notes was changed from October 19, 2012 to February 16, 2013 or such earlier date on which demand is made by the Required Holders. No other changes were made to the Notes with this amendment.

On December 14, 2012, completed a private placement of 10 "Units" at a price of \$100,000 per Unit, for aggregate gross consideration of \$1 million (the "Offering"), pursuant to a Securities Purchase Agreement (the "Purchase Agreement") dated as of December 11, 2012. Each Unit consisted of (i) 13,846,945 shares of the Company's common stock, par value \$.001 per share ("Common Stock"), (ii) 1,000 shares of Series A Convertible Preferred Stock of the Company (the "Preferred Shares"), each such Preferred Share being initially convertible into 17,718.52 shares of Common Stock, and (iii) 10-year Common Stock Purchase Warrants (the "Warrants"), to purchase 12,626,184 shares of Common Stock at an exercise price of \$0.003168 per share. Upon completion of Offering, there were issued and outstanding approximately 577,000,000 shares of Common Stock on a fully-diluted basis, of which 315,654,607 (or 70%) were issued in the Offering. The Company's Certificate of Incorporation only authorizes the issuance of 250,000,000 shares of Common Stock. The Preferred Shares issued in the Offering, which are convertible into an aggregate of 177,185,153 shares of Common Stock, will automatically convert into shares of the Common Stock on the date the Company files an amendment to its Certificate of Incorporation increasing the authorized number of shares of Common Stock and/or effecting a reverse stock split so that the Company has a sufficient number of authorized and unissued shares of Common Stock so as to permit the conversion of all outstanding Preferred Shares and all other convertible securities of the Company.

Based on the fact that the Company does not have enough authorized shares, the warrants will be accounted as liability instruments and valued at the fair value and marked to market. As of January 31, 2013, the fair value of the warrants amounted to \$5,050,474.

In connection with the Offering, and as a condition precedent thereto under the Purchase Agreement, the holders of a majority in principal amount (the "Requisite Holders") of the Company's outstanding 5% Senior Secured Convertible Promissory Notes (the "Notes"), entered into a Consent and Waiver (the "Consent") under which (i) the Notes were amended to provide for the automatic conversion of the outstanding principal and interest of all of the Notes upon the election of the Requisite Holders, (ii) the Requisite Holders elected to convert all outstanding principal and interest under the Notes, in the aggregate amount of \$3,891,838, into shares of Common Stock at a price \$0.15 per share (the conversion price under the Notes), and (iii) the exercise price of the Series B Warrants held by the holders of the Notes were reduced from \$0.25 per share to \$0.01 per share. The fair value of the convertible note at October 31, 2012 and November 30, 2012 amounted to \$243,731 and \$73,184, respectively. The fair value of the Series B Warrants amount to \$909,155 and \$852,784 at October 31, 2012 and January 31, 2013, respectively. The Required Holders consented to the Company's license of Onconase to James O. McCash ("McCash") and/or his affiliates (such licensee being referred to herein as the "Licensee"), on terms which include (i) the issuance to the Licensee of a warrant to purchase 23,750,000 shares of the Company's common stock at an exercise price of \$.01 per share, (ii) no other payments or other consideration provided, or expenditures incurred by, the Company to the Licensee in connection with such License, and (iii) the entry by McCash and affiliated stockholders of the Company into a general release in favor of the Company.

In connection with the Offering, the Company also entered into a Third Amendment to Investor Rights Agreement (the "Investor Rights Agreement Amendment") with the purchasers of the Units and the Requisite Holders under which the Company has provided registration rights with respect to the Common Stock issued in the Offering and the shares of Common Stock issuable upon conversion of the Preferred Shares and exercise of the Warrants.

On January 3, 2013, Lawrence A. Kenyon notified the Board that he intends to resign as President, Chief Executive Officer, Chief Financial Officer and Corporate Secretary of the Company as soon as practicable, in order to pursue other interests. Mr. Kenyon remained in his current role until March 31, 2013.

On February 5, 2013, Charles Muniz was removed as a director on the Board pursuant to an action by written consent of the stockholders constituting over a majority of the outstanding capital stock entitled to vote at an election of directors in accordance with Article II, Section 10 and Article III, Section 14 of the By-Laws. In addition, Fred Knoll, Patrick Ostronic and Ms. Sulley were elected by the requisite stockholders' vote to the Board to fill the existing vacancies on the Board and to serve in such positions until the next annual meeting of stockholders or until their earlier removal or resignation. Dr. David Sidransky will remain the Chairman of the Board. Fred Knoll is the principal of Knoll Capital and an affiliate of one of the principal stockholders, Europa International, Inc. Patrick Ostronic is affiliated with Unilab LP, another principal stockholder.

The SEC has commenced an administrative proceeding against the Company alleging the Company is delinquent in filing its periodic filings with the SEC since the Company has not filed any of its periodic reports since the quarterly report on Form 10-Q filed for the period ended January 31, 2011. The purpose of the hearing is to determine whether it is appropriate for the SEC to suspend for a period of up to 12 months or to permanently revoke the registration of the Company's common stock pursuant to Section 12 of the Securities Exchange Act of 1934. This action was instituted concurrently with a temporary suspension of trading of the common stock ordered by the SEC from January 25, 2013 through February 7, 2013.