UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

**FORM 10-K**

[X] ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended **September 30, 2011**

[ ] TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT

For the transition period from _____ to _____

Commission file number: **333-146834**

**Regenicin, Inc.**
(Exact name of registrant as specified in its charter)

| **Nevada** | **27-3083341** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| **10 High Court, Little Falls, NJ** | **07424** |
| (Address of principal executive offices) | (Zip Code) |

Registrant's telephone number: **(646) 403-3581**

Securities registered under Section 12(b) of the Exchange Act

| Title of each class | Name of each exchange on which registered |
|---|---|
| **none** | **not applicable** |

Securities registered under Section 12(g) of the Exchange Act:

Title of each class
**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 [X] No [ ]**

Indicate by checkmark 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 proceeding 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 [X] No [ ]**

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. **[X]**

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.

**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]**

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter. **$7,752,000**

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. **83,807,964 shares as of January 5, 2012.**

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## PART I

### Item 1. Business

**Overview**

We intend to develop and commercialize a potentially lifesaving technology by the introduction of tissue-engineered skin substitutes to restore the qualities of healthy human skin for certain clinical diagnoses. To this end, we have entered into an agreement to purchase stock of Cutanogen Corporation ("Cutanogen") from Lonza Walkersville, Inc. ("Lonza") (See Lonza Transaction below) and for the exclusive license to use certain proprietary know-how and information necessary to develop and seek approval by the U.S. Food and Drug Administration ("FDA") for the commercial sale of several products. These products are aimed at the treatment of burns, chronic wounds and a variety of plastic and reconstructive surgical procedures. In the United States market alone, the company estimates the potential markets for severe burns and chronic skin wounds is in excess of $7 billion.

The first product, PermaDerm™ is the only tissue-engineered skin prepared from autologous (patient's own) skin cells. It is a combination of cultured epithelium with a collagen-fibroblast implant that produces a skin substitute that contains both epidermal and dermal components. This model has been shown in preclinical studies to generate a functional skin barrier and in clinical studies to promote closure and healing of burns. Critically, we believe self-to-self skin grafts for permanent skin tissue are not rejected by the immune system of the patient, unlike with porcine or cadaver grafts in which immune system rejection is an important possibility. PermaDerm™ was initially designated as an Orphan Device by the FDA for treatment of burns. We have applied to the FDA this year for an Orphan designation as a biologic for PermaDerm™. If received, this would allow us to move forward to gain a Biological License Application Approval which would allow Regenicin to sell PermaDerm™ in certain defined markets.

The second product is anticipated to be, TempaDerm™. TempaDerm™ uses cells obtained from human donors to allow the development of banks of cryopreserved (frozen) cells and cultured skin substitute to provide a continuous supply of non-allogenic skin substitutes. This product has applications in the treatment of chronic skin wounds such as diabetic ulcers, decubitus ulcers and venous stasis ulcers. The U.S. markets are estimated to total more than $7 billion annually. This product is in the early development stage and does not have FDA approval.

We believe the technology has many different uses beyond the burn indication. The other uses include chronic wounds, reconstructive surgery and the individual components of the PermaDerm™ technology such as tendon wraps made of collagen or temporary coverings to protect the patients from infections while waiting for PermaDerm™. The collagen technology used for PermaDerm™ is a wide-open field in wound healing and uses such as stem cell grafting substrates. It is important to know that all of these above are products by themselves regardless of whether PermaDerm™ is approved for burns. We could pursue any or all of them independently if financing permitted. Even if PermaDerm™ was not approved for burn treatments it could be approved for chronic wounds or reconstruction.

We will need to raise capital to fund benchmark payments agreed to under the Lonza agreement. Upon receipt of Orphan Product BLA Approval (Pediatric), we will initiate sales with manufacturing performed by Lonza (See Lonza Transaction below). We hope to initiate clinical trials early 2012 with final submission to the FDA for approval for PermaDerm™ anticipated by 2013.

**Lonza Transaction**

We have entered into an agreement with Lonza Walkersville, Inc. ("Lonza") for the exclusive license to use certain proprietary know-how and information necessary to develop and seek approval by the U.S. Food and Drug Administration ("FDA") for the commercial sale of engineered skin substitute products. Lonza is a supplier to the pharmaceutical, healthcare and life science industries. Lonza produces and supports active pharmaceutical ingredients both chemically as well as biotechnologically. We paid Lonza $3 million for this exclusive license and stock purchase agreement.

***The Agreement***

The agreement with Lonza contemplates that, upon receipt of the full FDA approval, in the second stage of the transaction, we will execute a Stock Purchase Agreement pursuant to which we will purchase all of the outstanding stock of Cutanogen from Lonza for an additional purchase price of $2 million. Cutanogen holds certain patents ("Cutanogen Patents") and exclusive licenses (the "Cutanogen Licenses") to patent rights ("Patent Rights") owned by The Regents of the University of California and the University of Cincinnati and the Shriners Hospital for Children related to the commercialization of PermaDerm™. Upon our acquisition of Cutanogen, we will obtain beneficial use of the Cutanogen Licenses. The beneficial use will extend globally.

Included in the initial payment made under the Know-How License Agreement is assistance from Lonza to seek approval from the FDA to enable the commercial sale of PermaDerm™ in the U.S., and later for approval in foreign jurisdictions for commercial sale of PermaDerm™ throughout the world. We intend to create and implement a strategy to conduct human clinical trials and to assemble and present the relevant information and data in order to obtain the necessary BLA approvals for PermaDerm™ and possible related products.

When Lonza acquired Cutanogen, it inherited milestone payment obligations to the former Cutanogen shareholders in the total amount of up to $4.8 million. These payments are owed as PermaDerm™ is moved through the FDA approval process. As a result, our deal with Lonza will ultimately include paying those milestones plus the $2 million to Lonza.

The table below sets forth the milestone payments that may be required to expend to acquire the Cutanogen Licenses for commercialization.

| Milestone | Regenicin to pay to Lonza | Lonza to pay Cutanogen | Service provided or rights transfer |
|---|---|---|---|
| Initial Payment 31st July 2010 paid | $3, 000,000 | NA | Contract for know how license and exclusive ability to purchase Cutanogen Corporation |
| Submission Orphan application (pediatric) | $650,000 | $650,000 | Milestone payment to Cutanogen |
| Orphan approval (pediatric) | $650,000 | $650,000 | Milestone payment to Cutanogen |
| First commercial sale | $1,000,000 | $1,000,000 | Milestone payment to Cutanogen |
| Submission of BLA application (Adult) | $1,000,000 | $1,000,000 | Milestone payment to Cutanogen |
| Approval of BLA: New Biologic Approval (NBA) (Adult); | $1,500,000 | $1,500,000 | Milestone payment to Cutanogen |
| Full approval (NBA) | $2,000,000 | | Transfer of global licenses, know-how and patent rights to Regenicin. |

***Obligations under the Agreement***

Lonza's obligations under the agreement include the following: provide Know How (information in support of a clinical trial for PermaDerm™, including, without limitation, information relating to product specifications, manufacturing, testing, facilities, etc); and monitor prosecution and maintenance of patent rights and maintain the licenses under agreement relating to PermaDerm™.

Our obligations under the agreement include the following: reimburse Lonza for transferring Know-How; conduct pre-clinical and clinical trials; apply for and obtain approval from the FDA for commercial sales of PermaDerm™; and reimburse Lonza for monitoring prosecution of patent rights and for maintaining the licenses under agreement relating to PermaDerm™.

We are also obligated to pay Lonza 33% of the grant monies related to the clinical trial and commercialization of PermaDerm™.

***DOD Grant***

The U.S. Department of Defense has awarded to Lonza more than $16.9 million in funding for the development and commercialization of PermaDerm™ for the treatment of severe burns among U.S. troops and civilians. PermaDerm™ has already been used to treat more than 150 pediatric catastrophic burn victims through an Investigation Device Exemption (IDE) issued by the FDA. Submission for approval will take place in the near future when we are able to supply clinical data. The DOD supported clinical trial will include 10 adult males between the ages18 and 40 with full thickness burns over 50% of their Total Body Surface Area. The trial will commence upon approval of the IND by the FDA (explained below). The objective of the trial is to obtain Biological License Application (BLA) approval for adults and children.

The government grant received by Lonza Walkersville reduces our cost to get the product approved through the FDA. The contract awarded to Lonza covers two-thirds of the fees that we would typically be expected to pay for product development and clinical supplies. However, the DOD contract for $16.9 million is not only for PermaDerm™ development and clinical supplies; there are additional items in the contract for which Regenicin is not involved. These additional items include capital improvements, additional clinical sites, travel and administrative expenses, among others.

Once FDA approval is achieved and we acquire Cutanogen, Lonza will serve as our exclusive manufacturer and distributor and will be compensated for manufacturing.

Dispute regarding DOD Grant

Randall McCoy had been retained as a consultant by Cambrex Biosciences, the company that owned Cutanogen, which holds the license rights to PermaDerm™, to help in the regulatory process to gain FDA approval of PermaDerm™. When Lonza purchased Cambrex they also purchased Cutanogen. Lonza's core business is contract manufacturing of cell therapy bio medical products. They did not wish to pursue FDA approval or market the product. Mr. McCoy, understanding the value of the product and familiar with the regulatory process, offered to purchase the rights to the product. So we believe that Lonza entered into the Know-How and License Agreement (the "Agreement") because we have expertise in working with the FDA on the approval process and Lonza would rather function as a manufacturer.

There was a dispute between us and Lonza about payment on the DOD grant. The agreement obligates us to pay Lonza 33% of money received by Lonza as a result of any grant applications, including the application with the DOD. Lonza has billed us a total of $260,344 from November 30, 2010 to May 31, 2011 for what it believes it is owed under the agreement. We contend, however, that there was an overpayment of $201,197 in the original $3,000,000 that we already paid to Lonza, and this balance was to be applied to future invoices for amounts due by us under the agreement. Therefore, we believe that Lonza should apply the overpayment amount of $201,197 to the invoices totaling $260,344 to offset the balance. Lonza denies that there are any overpaid amounts under the agreement to offset the invoices and has requested that we pay the invoices.

In order to avoid a conflict with an important contractual partner in the pursuit of our business model, however, we have decided to pay Lonza the invoices in full. We therefore wired Lonza $260,344 to clear the balance, and have reserved our right to review the matter with Lonza at a later date.

The potential impact to us if either party breach a material provision of the Agreement depends on a number of factors, including the nature of the breach, whether the defaulting party is properly notified of the breach, whether the defaulting party fails to cure the breach within the timeframe allowed by the agreement, and the outcome of negotiations and perhaps legal battles concerning how to remedy the breach. Depending on the magnitude of the breach and how the parties react to the breach, the potential impact could vary from a minor disagreement that gets resolved by the parties to termination of the agreement with protracted litigation that bankrupts our company.

*Performance Evaluation*

Our performance and compliance with the agreement will be evaluated by the ability to move the PermaDerm™ candidate through the FDA approval path. If PermaDerm™ does not get approved then Lonza will not get paid the final $2 million agreement under the Stock Purchase Agreement and Cutanogen will not receive all milestone payments.

*Manufacturing & Distribution*

In the second stage of the Lonza Transaction, it is anticipated that we will implement our Exclusive Manufacturing Agreement with Lonza for PermaDerm™ and Lonza will be compensated for manufacturing PermaDerm™. Because Lonza will retain such exclusive manufacturing and distribution rights, we believe that maintaining a good working relationship with Lonza will be critical for the success of our business.

A cGMP (Current Good Manufacturing Practices) facility contract manufacturer operated by Lonza, one of the world's leading suppliers to the pharmaceutical, healthcare and life science industries and the largest cell therapy manufacturer in the world, will be our exclusive manufacturing partner for PermaDerm™, TempaDerm™ and other related products. FDA approval requires that manufacturers be cGMPs. It is anticipated that manufacturing will take place in the United States (Maryland) for those products being used in the US. Lonza also has facilities in Belgium and Singapore that could be qualified to also manufacture product. Products will be normally shipped directly by Lonza to treating physicians.

**FDA Approval Process**

On March 14, 2011, Lonza received a letter from the Food and Drug Administration (FDA) explaining that PermaDerm™ has been designated as a combination product. A combination product is comprised of two or more regulated components which, in the case of PermaDerm™, include a biologic component and a drug component. The FDA based their determination on the fact that PermaDermTM consists in part of autologus skin cells (specifically epidermal keratinocltes and dermal fibroblasts), which are biological product components and Chondroitin-6-Sulfate (C-6-S) which they consider a drug component. C-6-S is a critical part of PermaDermTM processing. C-6-S is used in the preparation of the collagen matrix on which the engineered skin is grown.

It should be noted that Lonza filed the application for PermaDerm™ under the Medical Device category because the other current skin products used for catastrophic burn are presently being marketed as medical devices. However, due to the fact that PermaDerm™ is considered by the FDA to be the only permanent closing skin product for catastrophic burns, the FDA believes PermaDerm™ should be classified as a Biologic and because we use C-6-S in our processing PermaDerm™ should have a drug component. We were quite pleased that the FDA took the position that the application should be filed under the Biologics/Drug category.

This designation was not viewed as a disagreement with us, but a departure from past practice of putting skin products used for treating burns in the Medical Device category. Being designated as Biologics/Drug is actually very beneficial to us because it shows PermaDerm™ to be uniquely different from other products used to treat catastrophic burns. Because PermaDerm™ uses a chemical in its processing that affects the cells in the body, it is considered a drug even though it has not yet been determined to contain any drug component at time of use. It is considered a Biologic because it contains no synthetic components. PermaDerm™ is the only human permanent skin covering of natural cells whereas other products on the market may have synthetic components or animal components in an attempt to trigger skin growth to provide a covering.

The clinical trial procedures for obtaining FDA approval of a product in the Biologics category better resembles that of products in the Medical Device category; the steps are relatively the same but they typically do not require multiple phases of clinical trials that are required for products with Drug designations. A Drug designation requires a new drug application (NDA) and a biologics designation requires a biological license application (BLA). For NDA, there are additional testing requirements, including pharmacokinetics and pharmacodynamcis, dose ranging studies, dose escalation studies, and teratology (how it affects offspring), which do not normally have to be performed for a BLA.

We believe that having a Biologics designation will be easier to process with the FDA than a Medical Device category would. We will be dealing with the Biologics group at the FDA (CBER) -- a group that has a better grasp at understanding cell growth, cultures, and other particulars of cell biology -- than the personnel in the Medical Device group. This familiarity with the underlying science behind PermaDerm™ should be an advantage in the approval process.

***Biological License Application***

As for the Orphan Biological License Application (BLA) Approval in adults and pediactrics, the DOD grant is designed to cover the majority of the expenses related to the approval process. We expect that Lonza will receive payments during the next year from DOD to pay for the clinical trials and to cover the cost of fabricating the cultured skin product. Our burden of that expense, 33%, will be paid to Lonza as we are invoiced along the way.

We believe there is antidotal data from the previous child studies showing the product is safe. The clinical trials that we want to pursue now are designed to demonstrate statistical significance efficacy and safety. So we believe 18 patients will be adequate to demonstrate PermaDerm™ is safe and efficacious for burns. The BLA approval process is as follows.

1. Pre Investigational New Drug (IND) Meeting. This meeting is used to answer any questions the FDA has at the outset and to get agreement from the FDA on what needs to be supplied for product approved. Lonza and the Department of Defense held the pre-IND meeting and received answers from the FDA. As a result of the meeting, we had a better understanding as to what the FDA will be looking for in the application and approval process.
2. IND application. The document is being revised and waiting for data from an animal study before submitting to the FDA. The IND is asking the FDA for permission to treat patients with our candidate product Permaderm™ to treat full thickness burns covering greater than 50% Total Body Surface Area. The FDA is required to respond in 60 days but they typically respond in 30 to either ask questions or they allow you to start your clinical trial.
3. Clinical trial. If the FDA says that the applicant may proceed with the clinical trial, patients are treated and data is collected about safety and efficacy as you described in your protocol as submitted with your IND. The trial currently designed will use 10-18 patients. Although these patients will be observed for up to 1 year following treatment we will be able to report the safety and grafting results necessary for approval without the one year follow up data. The main part of the data to be looked at for approval along with the treatment period is, in our case, three months. After three months the balance of the time is an observation period. We do not expect to see anything significant during the observation period that would affect the outcome of the trial.
4. At the end of the clinical trial we will submit a Biological License Application. The FDA will typically review and respond within 180 days when there is a minimum amount of data. This data is considered minimum in our case compared to some drugs which have patient data of thousands of people. Our study is very straight forward either the graft is positive on the patient or it is required to be grafted again. We have observed very positive results when treating children so we are quite optimistic that it will be able to demonstrate efficacy with a minimum number of patients. So it is possible to have approval in 2013. Efficacy would be defined as the graft adhered to the patient wound and remained viable similar to a split thickness Allograft.

***Orphan Application***

As to the Orphan product approval, we believe that the cost will be minimal. In a conference call, the FDA informed Lonza that it requires a mouse study of the product grown in Walkersville on mice to demonstrate the product is safe. The FDA stated that this mouse study would help demonstrate that PermaDerm is safe when made in a fully compliant cGMP facility. The final mouse study is scheduled to start in Jan 2012. The product for the animal study will be manufactured at Lonza and then transported to an animal testing facility where the product will be grafted into mice and evaluated. The FDA requires that the manufacturing site that will be supplying commercial product be the same site used to manufacture product for the Preclinical studies and Clinical trials. The cost associated with this mouse study is estimated at $300,000 or less.

We intend to do the following for approval:

1. Request for Orphan Designation as a biologic/drug. We have applied to the FDA for an Orphan designation as a biologic for PermaDerm™. We anticipate the FDA will be responding in the near future.
2. We do need to conduct the animal study as described above before treating any human with PermaDerm made in the Lonza Walkersville facility.
3. Collect and assemble the safety and efficacy data from a small clinical trial using PermaDerm™ made at lonza with the current manufacturing process at Lonza and submit what is called a BLA Orphan application. The FDA has 180 days to respond to this BLA Orphan. If the product is for an unmet need or is life saving it may receive priority status review. If it is both a life saving product and there are no similar treatments it may be reviewed in about 75 days.

***Products and Technology***

Our products will utilize the emerging technology of tissue engineering by which cells and biopolymers are combined to generate devices for surgical therapy. These platform technologies combine technology for proliferation and cryopreservation of human skin cells with technology for fabrication of implantable collagen, the main structural fiber in the body. A proprietary collagen sponge is prepared and skin cells are added to produce a skin substitute that can be grafted surgically to wounds and result in permanent skin repair. For treatment of acute wounds (burns, plastic surgery), autologous cells (i.e., where the recipient is donor) are transplanted and reform their own skin tissue that is not rejected. For treatment of chronic wounds (leg ulcers, bed sores), either autologous or allogenic cells (i.e., where the recipient is not donor) are transplanted to provide wound closure and stimulate permanent healing.

Prototypes of products have been used successfully to treat catastrophic burn injuries, chronic wounds and congenital skin pathologies. Preliminary data will be collected under a study monitored by The FDA. Once a product receives an Orphan designation, we the developer of the product is guaranteed seven years market exclusivity for a specific indication following the product's approval by the FDA.

Unique features of the platform technologies include:

- easier fabrication and superior storage because of modular design
- better compliance with pharmaceutical standards for medical products through use of low-serum or serum-free media
- establishment of a functional epidermal barrier at the time of grafting
- sufficient versatility to allow simultaneous delivery of cells and drugs
- compatible designs for gene therapy for future generations of products
- engineered skin graft with dermal and epidermal components from autologous cells.

Clinical advantages of these platform technologies may include, but are not limited to:

- fewer surgeries to complete wound closure
- shorter hospitalization
- closure of non-healing wounds
- less host rejection
- less need for re-grafting
- no need for immuno-suppression as with other therapies
- reduced pain and scarring from harvesting of donor sites

These unique features and clinical advantages are believed to provide a competitive advantage in wound care markets.

Potential customers for our products are physicians or hospitals who order or recommend our products for patients with open wounds and burns. The decision to purchase is based on the medical needs of the patient, and the alternatives available to the physician to successfully satisfy those needs. Many patients with burns and chronic wounds suffer extensively because effective treatments for wound closure are not available to the treating physicians. Therefore, if an effective therapy is available to treat wounds that otherwise remain open; the physician's decision is simple medically. Although the cost of cell therapy is relatively high, it is far less than the cost of persistent open wounds.

Two initial product lines are planned based on these core technologies: PermaDerm™, and TempaDerm™. It is our plan to first commercialize PermaDerm™, with the commercialization of TempaDerm™ to follow.

***PermaDermTM***

PermaDerm™ is the only tissue-engineered skin prepared from autologous (patient's own) skin cells. It is a combination of cultured epithelium with a collagen-fibroblast implant that produces a skin substitute that contains both epidermal and dermal components. This model has been shown in preclinical studies to generate a functional skin barrier and in clinical studies to promote closure and healing of burns. Critically, we believe self-to-self skin grafts for permanent skin tissue are not rejected by the immune system of the patient, unlike with porcine or cadaver grafts in which immune system rejection is an important possibility. PermaDerm™ was initially designated as an Orphan Device by the FDA for treatment of burns. We applied to the FDA for an Orphan designation as a biologic for PermaDerm™. If received this would allow us to move forward to gain an Orphan Biological License Application Approval which would allow Regenicin to sell PermaDerm™ in certain defined markets.

**United States Severe Burn Market** - According to data published in the American Burn Association; Journal of Burn Care & Rehabilitation (May/June), there are currently over 4,000 cases annually with burns over 50% of the patient's total body surface area (TBSA). PermaDerm™ is the only medical product known at present for treatment of full-thickness burns with autologous cells. It is anticipated that the use of PermaDerm™ will reduce healthcare costs by decreasing a patient's stay in the critical care unit by reducing the need for additional surgeries.

**Sales and Marketing** – Because care for serious open wounds and burns is concentrated in a relatively small number of treatment centers, we believe that after we obtain FDA approval we will be able to commercialize the product in the U.S. with relatively few marketing and sales personnel. The PermaDerm™ product does not require additional training of the physicians as it is applied the same as porcine, cadaver or split thickness grafts. Initial marketing will be compromised of a two person education effort. We will identify and train two highly competent (East Coast and West Coast) individuals to in-service the 125 certified burn centers in the proper patient identification and procedures for using PermaDerm™. We will complement this effort with promotional marketing and public relations campaigns. We intend to target Video news Releases (VNR), television HealthBeat segments and targeted professional journal advertisements.

***Additional Opportunities***

**Plastic and reconstructive surgery.** Recent clinical investigations have demonstrated feasibility for use of PermaDerm™ for reconstruction of wounds in patients who have recovered from massive burn injuries. Because this is the same medical indication (>50% total body surface area burns) as the primary indication for acute burns, it is expected that the regulatory path may be expedited. In addition, research has demonstrated successful use of PermaDerm™ for repair of congenital birth defects (giant nevus, amniotic constriction bands) in which skin grafts are required. These markets are expected to increase the sales of PermaDerm™ beyond acute burns.

**Future Opportunities** – We also intend to commercialize certain intrinsic elements of PermaDermTM. For example, PermaDerm™ uses a proprietary collagen sponge, called a biomedical matrix, to act as a connective agent in the skin generation process. This biomedical matrix can be used for a variety of applications outside of the production of PermaDerm™, including as:

- protection for organs and tendons
- a barrier for hormones or medicines
- a protective healing agent for wounds
- a carrier for stem cells

***TempaDerm™***

TempaDerm™ uses cells obtained from human donors to allow the development of banks of cryopreserved (frozen) cells and cultured skin substitute to provide a continuous supply of non-allogenic skin substitutes. This product has applications in the treatment of chronic skin wounds such as diabetic ulcers, decubitus ulcers and venous stasis ulcers. This product is in the early development stage and does not yet have FDA approval.

**United States Chronic Wounds Market** – A potential market of over $7 billion annually exists for treatment of chronic wounds (leg ulcers, bed sores, and diabetic ulcers. According to the National Pressure Ulcer Council (NOUP), chronic wounds have an incidence of 9% of the hospitalized population of those over 70 years old. At present

There is currently only cadaver or porcine skin that is approved for treatment of venous stasis and diabetic ulcers. However, venous stasis and diabetic ulcers do not represent the entire market for chronic wounds, and it remains under-served. Therefore, we believe that the majority of the chronic wound market remains under-served, and that substantial opportunity exists to capture a large segment of the total chronic wound market.

We intend to focus our resources on gaining regulatory approval for the use of our products in the treatment of chronic wounds, and to develop the widespread adoption of these technologies into the marketplace. Upon successful transfer of intellectual property and adequate funding, we will initiate clinical studies for TempaDerm™ with product introduction expected in 2014.

*Potential Future Markets*

The platform technologies may also be applied to research and diagnostic products. An additional major market for cultured skin substitutes is safety testing of consumer products to replace the use of animal testing. Two prospective licensees for this technology have been identified and a Letter of Intent is expected from both of these companies (one is the largest consumer products suppliers in the world).

*Skin Research.* Our products are sufficiently advanced to begin immediate marketing to research laboratories in government, industry and academics. These markets are considered smaller than the toxicology or surgery markets, but are sufficiently large to generate revenues to partially support initial operations.

*Competition*

Several companies have developed products that propose to approach the markets described above. Among those companies are:

- Smith & Nephew Wound Management
- Curative Health Services
- Genzyme Biosurgery
- Integra Life Sciences Corporation
- LifeCell Corporation
- Organogenesis Inc
- Ortec International, Inc
- Hy-Gene

Each of these companies has a proprietary approach to these markets, but none has yet penetrated the markets fully and only 2 companies, (Integra and Life Cell) have products that are FDA approved for use in burn patients. Conversely, our products are believed to be superior in design and function and, thus, provide significant advantages over the above competitors. The advantages of PermaDerm™ include simultaneous delivery of epidermal keratinocytes and fibroblasts on a prefabricated collagen implant. The FDA has stated that PermaDerm is the only permanent closing skin product. Cutanogen material has been utilized in pre-pivotal (Phase II level) studies that have been submitted to the FDA for review. We plan to initiate and conclude a pivotal (Phase III level) multi-center study for data collection in order to assist us to obtain full market approval.

*Government Regulation*

The Pediatric Medical Device Safety and Improvement Act of 2007 (Public Law 110-85) provides that Orphan Product applications for pediatric use only, or for use in both pediatric and adult patients, that are approved on or after September 27, 2007, are assigned an annual distribution number (ADN) and may be sold for profit (subject to the upper limit of the AND). In addition, once a product receives an Orphan BLA, the developer of the product receives up to seven years market exclusivity for a specific indication following the product's approval by the FDA. The Orphan designation also requires that there be no comparable product in the market place. If we submit a Full BLA application for the product, the Orphan designation, and related market exclusivity, could be terminated early.

Unrestricted sales of PermaDerm™ will require full approval after data for safety and efficacy are collected from a multi-center study. We will be discussing the design of the multicenter study with the FDA. Based on the proposed design, the study is estimated to require enrollment and treatment of not more than 10 to 18 patients, and follow-up for one year. Enrollment and treatment are expected to require one year. After collection of data and submission to FDA, six months is typically planned for FDA's review and decision. Having an Orphan designation of which the indication is life threatening and there is an unmet need the review time can be reduced significantly. Therefore, we plan that performance of the multi-center study and a decision from FDA less than 6 months after pre approval inspection of the manufacturing facility by FDA.

**Intellectual Property**

In August 2010, we paid $7,500 and obtained the rights to the trademarks PermaDerm® and TempaDerm® from KJR-10 Corp.

**Employees**

As of December 31, 2011, we had 7 employees.

**Item 1A. Risk Factors.**

A smaller reporting company is not required to provide the information required by this Item.

**Item 1B. Unresolved Staff Comments**

A smaller reporting company is not required to provide the information required by this Item.

**Item 2. Properties**

Our principal executive offices are located at 10 High Court, Little Falls, NJ07424. Our headquarters is located in the offices of McCoy Enterprises LLC, an entity controlled by Randall McCoy, our Chief Executive Officer. The office is attached to his residence but has its own entrances, restroom and kitchen facilities. No rent is charged.

We also maintain an office at 3 Arviba Drive, Pennington NJ 08534, which is our materials and testing laboratory. This office is owned by Materials Testing Laboratory, and the principal is an employee of our company. No rent is charged.

**Item 3. Legal Proceedings**

Aside from what follows, we are not a party to any pending legal proceeding. We are not aware of any pending legal proceeding to which any of our officers, directors, or any beneficial holders of 5% or more of our voting securities are adverse to us or have a material interest adverse to us.

On February 28, 2011, our board of directors, Mr. Randall McCoy, and our company (collectively the "Plaintiffs") filed an amended complaint in the Eighth Judicial District Court of Nevada (Case No. A-11-634976-C) against Joseph Connell, our former President. The Plaintiffs in the amended complaint are requesting declaratory relief from certain allegations Mr. Connell has made in relation to partnership claims with Mr. McCoy, board membership, and stock ownership in our company. Mr. Connell has requested that the case be removed to federal court in Nevada and has requested that our complaint be dismissed for lack of jurisdiction.

On March 11, 2011, Mr. Connell filed a complaint in the Supreme Court of the State of New York (Index No. 103007/11) against Mr. Mccoy, Regenicin, Inc., Joseph Rubinfeld, John Weber and Craig Eagle. The complaint alleges, among other things, that Mr. Connell is entitled to 50% of Mr. McCoy's stock in our company. The complaint requests an accounting from us and requests that we be enjoined from transferring title to Mr. McCoy's shares.

On June 8, 2011, an agreement was reached (the "Agreement") to dismiss the members of the Company's board of directors (excluding Mr. McCoy) and the Company from the case currently pending in the United States District Court for the Southern District of New York. As part of this Agreement, the Company also agreed to dismiss its action originally brought against Mr. Connell in the United States District Court for the District of Nevada. Since then, the dispute continued involving only Mr. Connell and Mr. McCoy as parties in the action pending in the United States District Court for the Southern District of New York. As part of the Agreement, Mr. McCoy has agreed to lock-up 25,000,000 of his personal shares pending the outcome of the case.

On November 17, 2011, there was a formal settlement conference before a Magistrate Judge. At that conference, an agreement was reached in principle, with the details to be worked out and a settlement agreement signed on or before January 25. The settlement agreement has not been signed as of the date of this Annual Report.

**Item 4. (Removed and Reserved)**

## PART II

**Item 5. Market for Registrant's Common Equity and Related Stockholder Matters and Issuer Purchases of Equity Securities**

**Market Information**

Our common stock is currently quoted on the OTC Bulletin Board ("OTCBB"), which is sponsored by FINRA. The OTCBB is a network of security dealers who buy and sell stock. The dealers are connected by a computer network that provides information on current "bids" and "asks", as well as volume information. Our shares are quoted on the OTCBB under the symbol "RGIN."

The following table sets forth the range of high and low bid quotations for our common stock for each of the periods indicated as reported by the OTCBB. These quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

Fiscal Year Ending September 30, 2010

| Quarter Ended | High $ | Low $ |
|---|---|---|
| September 30, 2010 | 2.50 | 1.85 |
| June 30, 2010 | N/A | N/A |
| March 31, 2010 | N/A | N/A |
| December 31, 2009 | N/A | N/A |

Fiscal Year Ending September 30, 2011

| Quarter Ended | High $ | Low $ |
|---|---|---|
| September 30, 2011 | 0.232 | 0.11 |
| June 30, 2011 | 0.32 | 0.1151 |
| March 31, 2011 | 0.83 | 0.2101 |
| December 31, 2010 | 1.50 | 0.42 |

**Stock Splits**

On July 19, 2010, we declared a stock split of thirty-four (34) to one (1) in which each stockholder was issued thirty-four common shares in exchange for each one common share of their currently issued common stock. The stock split was declared effective by FINRA on August 2, 2010.

**Penny Stock**

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a market 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, to deliver a standardized risk disclosure document prepared by the SEC, that: (a) contains a description of the nature and level of risk in the market for penny stocks in both public offerings and secondary trading; (b) contains a description of the broker's or dealer's duties to the customer and of the rights and remedies available to the customer with respect to a violation of such duties or other requirements of the securities laws; (c) contains a brief, clear, narrative description of a dealer market, including bid and ask prices for penny stocks and the significance of the spread between the bid and ask price; (d) contains a toll-free telephone number for inquiries on disciplinary actions; (e) defines significant terms in the disclosure document or in the conduct of trading in penny stocks; and (f) contains such other information and is in such form, including language, type size and format, as the SEC shall require by rule or regulation.

The broker-dealer also must provide, prior to effecting any transaction in a penny stock, the customer with (a) bid and offer quotations for the penny stock; (b) the compensation of the broker-dealer and its salesperson in the transaction; (c) the number of shares to which such bid and ask prices apply, or other comparable information relating to the depth and liquidity of the market for such stock; and (d) a monthly account statement showing 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 acknowledgment of the receipt of a risk disclosure statement, a written agreement as to transactions involving penny stocks, and a signed and dated copy of a written suitability statement.

These disclosure requirements may have the effect of reducing the trading activity for our common stock. Therefore, stockholders may have difficulty selling our securities.

**Holders of Our Common Stock**

On October 27, 2010, we increased the number of authorized shares of common stock from 90,000,000 shares to 200,000,000 by amending our Articles of Incorporation. As of September 30, 2011, we had 83,807,964 shares of our common stock issued and outstanding, held by one hundred and six (106) shareholders of record.

***Dividends***

There are no restrictions in our articles of incorporation or bylaws that prevent us from declaring dividends. The Nevada Revised Statutes, however, do prohibit us from declaring dividends where after giving effect to the distribution of the dividend:

1. we would not be able to pay our debts as they become due in the usual course of business, or;
2. our total assets would be less than the sum of our total liabilities plus the amount that would be needed to satisfy the rights of shareholders who have preferential rights superior to those receiving the distribution.

We have not declared any dividends and we do not plan to declare any dividends in the foreseeable future.

**Recent Sales of Unregistered Securities**

There have been no issuances of securities without registration under the Securities Act of 1933 during the reporting period, which were not previously included in a Quarterly Report on Form 10-Q or Current Report on Form 8-K.

**Securities Authorized for Issuance under Equity Compensation Plans**

On December 15, 2010, the board of directors approved the Regenicin, Inc. 2010 Incentive Plan (the “Plan”). The Plan provides for the granting of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock, stock units, performance shares and performance units to our employees, officers, directors and consultants, including incentive stock options, non-qualified stock options, restricted stock, and other benefits. The Plan provides for the issuance of up to 4,428,360 shares of our common stock.

On January 6, 2011, we approved the issuance of 885,672 options to each of the four members of the board of directors at an exercise price is $0.62 per share. The options vest over a three-year period and expire on December 22, 2015. On May 11, 2011, the terms of the options were amended to allow for immediate vesting.

In addition, we approved the issuance of 2,000,000 options to a consultant at an exercise price of $0.46 per share. The options vested immediately and expire in November 2015.

| Plan Category | Number of securities to be issued upon exercise of outstanding option, warrants and rights | Weighted-average exercise price of outstanding options, warrants and rights | Number of securities remaining available for future issuances under equity compensation plans |
|---|---|---|---|
| Equity compensation plans approved by security holders | 0 | 0 | 0 |
| Equity compensation plans not approved by security holders | 5,542,688 | $ 0.56 | 0 |
| Total | 5,542,688 | $ 0.56 | 0 |

**Item 6. Selected Financial Data**

A smaller reporting company is not required to provide the information required by this Item.

**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

**Forward-Looking Statements**

Certain statements, other than purely historical information, including estimates, projections, statements relating to our business plans, objectives, and expected operating results, and the assumptions upon which those statements are based, are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements generally are identified by the words "believes," "project," "expects," "anticipates," "estimates," "intends," "strategy," "plan," "may," "will," "would," "will be," "will continue," "will likely result," and similar expressions. We intend such forward-looking statements to be covered by the safe-harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995, and are including this statement for purposes of complying with those safe-harbor provisions. Forward-looking statements are based on current expectations and assumptions that are subject to risks and uncertainties which may cause actual results to differ materially from the forward-looking statements. Our ability to predict results or the actual effect of future plans or strategies is inherently uncertain. Factors which could have a material adverse affect on our operations and future prospects on a consolidated basis include, but are not limited to: changes in economic conditions, legislative/regulatory changes, availability of capital, interest rates, competition, and generally accepted accounting principles. These risks and uncertainties should also be considered in evaluating forward-looking statements and undue reliance should not be placed on such statements. We undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise. Further information concerning our business, including additional factors that could materially affect our financial results, is included herein and in our other filings with the SEC.

**Results of Operations for the Years Ended September 30, 2011 and 2010**

We generated no revenues from September 6, 2007 (date of inception) to September 30, 2011. We do not expect to generate revenues until we are able to obtain FDA approval of PermaDerm™, and thereafter acquire the license rights to sell products associated with that technology.

We incurred operating expenses of $3,658,707 for the year ended September 30, 2011, compared with operating expenses of $679,144 for the year ended September 30, 2010. Our operating expenses increased in 2011 from 2010, as a result of ramping up operations in connection with our tissue-engineered skin substitutes business, and are compared as follows:

| Operating Expenses | September 30, 2011 | September 30, 2010 |
|---|---|---|
| Legal and Accounting | $ 580,553 | $ 120,098 |
| Public Relations and Marketing Support | $ 327,099 | $ 231,234 |
| Salaries, Wages and Payroll Taxes | $ 817,870 | $ 124,653 |
| Consulting and Computer Support | $ 919,402 | $ 87,000 |
| Office Expenses and Miscellaneous | $ 41,017 | $ 59,194 |
| Travel | $ 84,409 | $ 27,334 |
| Insurance | $ 72,177 | $ 14,833 |
| Website Expenses | $ 5,704 | $ 14,798 |
| Research and Development | $ 518,902 | $ — |
| Registration Penalty | $ 250,203 | $ — |
| Employee Benefits | $ 41,371 | $ — |

We incurred stock based compensation of $867,726 and $0 for the years ended September 30, 2011 and 2010 from the issuance of common stock, warrants and options to our directors, officers and third-party consultants. Such amounts are included above under consulting.

We incurred other expenses of $6,875 for the year ended September 30, 2011, as compared to $256,106 for the year ended September 30, 2010. Our other expenses for both periods consisted of interest expense. The expense for 2010 included $251,514 to reflect the amortization of the beneficial conversion feature of Bridge Notes issued.

We incurred a net loss of $3,665,582 for the year ended September 30, 2011, as compared with a net loss of $935,250 for the prior year.

**Liquidity and Capital Resources**

As of September 30, 2011, we had total current assets of $78,026 and total assets in the amount of $3,085,526. Our total current liabilities as of September 30, 2011 were $1,467,821. We had a working capital deficit of $1,389,795 as of September 30, 2011. Our cash was $4,396 as of September 30, 2011.

Operating activities used $1,774,552 in cash for the year ended September 30, 2011. The decrease in cash was primarily attributable to funding the loss for the year.

Financing activities provided $1,774,384 for the year ended September 30, 2011 and consisted of $467,550 in proceeds from the sale of common stock, $1,180,000 in the sale of units of our Series A Convertible Preferred Stock and warrants, $115,000 in proceeds from notes payable, $187,211 in advances from related parties, and $145,000 in loans payable, offset by $75,777 in expenses related to the sale of our common stock, $9,600 in expenses related to the sale of our Series A Convertible Preferred Stock and $235,000 in the repayment of notes payable.

Based upon our current financial condition, we do not have sufficient cash to operate our business at the current level for the next twelve months. We intend to fund operations through increased sales and debt and/or equity financing arrangements, which may be insufficient to fund expenditures or other cash requirements. We plan to seek additional financing in a private equity offering to secure funding for operations. There can be no assurance that we will be successful in raising additional funding. If we are not able to secure additional funding, the implementation of our business plan will be impaired. There can be no assurance that such additional financing will be available to us on acceptable terms or at all.

The primary short term objective of the company is to gain FDA approval for both the pediatric and adult indications for the use of PermaDerm™. Understanding that these approvals are not contingent upon one another, but will be independent submissions, our most essential efforts and expenditures in the short term will be regulatory in nature. It should be noted that the regulatory expenditure related to adult indication will be substantially funded by the aforementioned government contract to Lonza, discussed above, 66% of clinical supplies, regulatory support and commercialization expenses are also covered by the government contract. The remaining expense, of the 33.3% to be absorbed by the company, is recognized as $130,000 per month in the Regulatory Expense category below. The regulatory expense related to pediatric indication is expected to be roughly $20,000 per month, due to the fact that over 100 patients have previously been treated with PermaDerm™, under a Humanitarian Use Device designation granted by the FDA. As a result, it is the opinion of management that not only will the expenditure be minimized but the time to approval will be greatly reduced. Commercial sales in the pediatric category are projected to begin within 12 month of funding.

| **The Current Monthly Expenditures are as follows:** | **Total** | **Regulatory** | **Required** |
|---|---|---|---|
| Salaries | $ 73,000 | $ 8,000 | 65,000 |
| Fringe Benefits | 5,000 | 1,000 | 4,000 |
| T&E | 10,000 | 5000 | 5,000 |
| Subtotal | 88,000 | 14,000 | 74,000 |
| | | | |
| clinical trials | 130,000 | 130,000 | |
| Pediatric | 20,000 | 20,000 | |
| Regulatory Expense subtotal | $ 150,000 | 150,000 | |
| | | | |
| Professional Fees: | | | |
| Legal | 12,500 | | 12,500 |
| Accounting & Audit | 6,500 | | 6,500 |
| Subtotal | $ 19,000 | | $ 19,000 |
| | | | |
| Public Relations | $ 12,000 | | 12,000 |
| | | | |
| Insurance | $ 7,500 | | 7,500 |
| | | | |
| Miscellaneous | 3,500 | 1,500 | 2,000 |
| | | | |
| Total | $ 280,000 | $ 165,500 | $ 114,500 |

As can be noted from the above schedule, management estimates the current total monthly expense at approximately $280,000. A further analysis of this total monthly amount indicates that the minimum regulatory expense required to meet the objectives, without delay, in the next 12 months is estimated at $165,500, with an additional minimum monthly expense to meet statutory requirements of $114,500. In summary, in order to continue operations meeting only the regulatory schedule and statutory requirements would cost approximately $280,000 per month.

Currently, we are hopeful that we will close on a new round of financing in the $2-$4 million range within the next 30 - 60 days. In addition, shareholder, directors, and officers have contributed capital in the past and it is expected that they will continue if required. Finally, creditors have also been willing to extend terms when necessary and employees have accepted delayed payment.

For the first full year, after the approval of the pediatric indication, we are projecting revenue in the United States in excess of $10 million. Lead pricing from our manufacturer, Lonza, would yield gross contribution of approximately $4 million. This does not include any international licensing revenue opportunities, in which interest has been exhibited. It is also the opinion of management that since there are over 125 major burn centers in the U.S., marketing and selling expense will be minimal. It should also be noted, that Perma DermTM's grafting procedure is similar to the current method used with skin substitutes. As a result, the surgeon training will be minimal. In addition, due to the fact that Lonza, our contract manufacturer, will handle the patients' skin sample, manufacture the PermaDermTM, and deliver the product directly to the surgeon, the company's distribution and manufacturing expense will be minimal. Finally, due to PermaDerm TM being autologous, (made from the patient's own skin), rejection, infection, and time in the intensive unit can be greatly reduced.

**Off Balance Sheet Arrangements**

As of September 30, 2011, there were no off balance sheet arrangements.

**Going Concern**

Our financial statements have been prepared assuming that we will continue as a going concern which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We have incurred cumulative losses of $4.7 million for the period September 6, 2007 (inception date) through September 30, 2011, expect to incur further losses in the development of our business and have been dependent on funding operations through the issuance of convertible debt and private sale of equity securities. These conditions raise substantial doubt about our ability to continue as a going concern. Management’s plans include continuing to finance operations through the private or public placement of debt and/or equity securities and the reduction of expenditures. However, no assurance can be given at this time as to whether we will be able to achieve these objectives. The financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

**Critical Accounting Policies**

In December 2001, the SEC requested that all registrants list their most “critical accounting polices” in the Management Discussion and Analysis. The SEC indicated that a “critical accounting policy” is one which is both important to the portrayal of a company’s financial condition and results, and requires management’s most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain.

***Development Stage Activities and Operations:***

The Company is in the development stage and has had no revenues. A development stage company is defined as one in which all efforts are devoted substantially to establishing a new business and even if planned principal operations have commenced, revenues are insignificant.

***Intangibles Assets:***

Intangible assets, which include purchased licenses, patents and patent rights, are stated at cost and will be amortized using the straight-line method over their useful lives based upon the pattern in which the expected benefits will be realized, or on a straight-line basis, whichever is greater.

We review our intangible assets subject to amortization whenever events or changes in circumstances indicate that the carrying amount of such an asset may not be recoverable. Recoverability of these assets is measured by comparison of their carrying amount to the future undiscounted cash flows the assets are expected to generate. If such assets are considered impaired, the impairment to be recognized is equal to the amount by which the carrying value of the assets exceeds their fair value determined by either a quoted market price, if any, or a value determined by utilizing a discounted cash flow technique. In assessing recoverability, we must make assumptions regarding estimated future cash flows and discount factors. If these estimates or related assumptions change in the future, we may be required to record impairment charges.

**Recently Issued Accounting Pronouncements**

In June 2011, the FASB issued ASU No. 2011-05, "*Comprehensive Income (Topic 220): Presentation of Comprehensive Income (ASU 2011-05)*." ASU 2011-05 provides that an entity that reports items of other comprehensive income has the option to present comprehensive income in either one continuous financial statement or two consecutive financial statements. ASU 2011-05 is effective for annual periods beginning after December 15, 2011. We do not expect ASU 2011-05 to have any impact on our financial position and results of operations.

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

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

A smaller reporting company is not required to provide the information required by this Item.

**Item 8. Financial Statements and Supplementary Data**

Index to Financial Statements Required by Article 8 of Regulation S-X:

**Audited Financial Statements:**

**F-1 Report of Independent Registered Public Accounting Firm**
**F-2 Consolidated Balance Sheets as of September 30, 2011 and 2010**
**F-3 Statements of Operations for the years ended September 30, 2011 and September 30, 2010, and the period from inception to September 30, 2011**
**F-4 Statement of Stockholders' Equity for period from inception to September 30, 2011**
**F-5 Statements of Cash Flows for the years ended September 30, 2011 and September 30, 2010, and the period from inception to September 30, 2011**
**F-6 Notes to Financial Statements**

## REPORT OF INDEPENDENT REGISTERED ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Regenicin, Inc.

We have audited the accompanying balance sheets of Regenicin, Inc. (a development stage company) (the "Company") as of September 30, 2011 and 2010 and the related statements of operations, changes in stockholders' equity and cash flows for the years then ended and for the period from September 6, 2007 (inception date) through September 30, 2011. The 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. The statements of operations, changes in stockholders' equity (deficiency) and cash flows of the Company for the period from September 6, 2007 (inception date) through September 30, 2009 were audited by other auditors whose report dated January 6, 2010 on those statements included an explanatory paragraph describing conditions that raised substantial doubt about the Company's ability to continue as a going concern

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). These 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 its internal control over financial reporting. Our audit included consideration of 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 also 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, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of September 30, 2011 and 2010 and the results of their operations and cash flows for the years then ended and for the period from September 6, 2007 (inception date) through September 30, 2011 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 A to the financial statements, the Company has incurred losses, expects to incur further losses in the development of its business and has been dependent on funding operations through the issuance of convertible debt and private sale of equity securities. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans concerning these matters are also described in Note A. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/S/ ROTENBERG MERIL SOLOMON BERTIGER & GUTTILLA, P.C.

ROTENBERG MERIL SOLOMON BERTIGER & GUTTILLA, P.C.
Saddle Brook, New Jersey

January 12, 2012

REGENICIN, INC.
(A Development Stage company)
BALANCE SHEETS

| ASSETS | September 30, 2011 | September 30, 2010 |
|---|---|---|
| CURRENT ASSETS | | |
| Cash | $ 4,396 | $ 4,564 |
| Prepaid expenses and other current assets | 73,630 | 25,970 |
| Total current assets | 78,026 | 30,534 |
| Intangible assets | 3,007,500 | 3,007,500 |
| Total assets | $ 3,085,526 | $ 3,038,034 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| CURRENT LIABILITIES | | |
| Accounts payable | $ 739,327 | $ 221,762 |
| Accrued expenses | 658,251 | 138,985 |
| Loans payable | 10,000 | — |
| Note payable | 60,243 | 150,000 |
| Due to related party | — | 318,789 |
| Total current liabilities | 1,467,821 | 829,536 |
| Total liabilities | 1,467,821 | 829,536 |
| COMMITMENTS AND CONTINGENCIES | | |
| STOCKHOLDERS' EQUITY | | |
| Preferred Stock, $0.001 par value 4,500,000 shares authorized; none outstanding | — | — |
| Series A 10% Convertible Preferred stock, $0.001 par value, 5,500,000 shares authorized; 1,345,000 and -0- issued and outstanding | 1,345 | — |
| Common stock, $0.001 par value;200,000,000 shares authorized; 88,236,324 and 86,406,257 issued; 83,807,964 and 86,406,257 outstanding | 88,237 | 86,407 |
| Additional paid-in capital | 6,192,883 | 3,116,841 |
| Deficit accumulated during development stage | (4,660,332) | (994,750) |
| Less: treasury stock; 4,428,360 shares at par | (4,428) | — |
| Total stockholders' equity | 1,617,705 | 2,208,498 |
| Total liabilities and stockholders' equity | $ 3,085,526 | $ 3,038,034 |

See Notes to Financial Statements

REGENICIN, INC.
(A Development Stage company)
STATEMENTS OF OPERATIONS

| | Year Ended September 30, 2011 | Year Ended September 30, 2010 | September 6, 2007 (Inception Date) Through September 30, 2011 |
|---|---|---|---|
| Revenues | $ — | $ — | $ — |
| Operating expenses | | | |
| Research and development | 518,902 | | 518,902 |
| General and administrative | 2,272,079 | 679,144 | 3,010,723 |
| Stock based compensation - general and administrative | 867,726 | — | 867,726 |
| Total operating expenses | 3,658,707 | 679,144 | 4,397,351 |
| Loss from operations | (3,658,707) | (679,144) | (4,397,351) |
| Other Income (Expenses) | | | |
| Interest expense, including amortization of beneficial conversion feature | (6,875) | (256,106) | (262,981) |
| Total Other Income (Expenses) | (6,875) | (256,106) | (262,981) |
| Net loss | (3,665,582) | (935,250) | (4,660,332) |
| Preferred stock dividends | (1,371,110) | — | (1,371,110) |
| Net loss attibutable to common stockholders | $ (5,036,692) | $ (935,250) | $ (6,031,442) |
| Basic and diluted loss per share: | $ (0.06) | $ (0.01) | |
| Weighted average number of shares outstanding | | | |
| Basic and diluted | 84,716,738 | 75,411,182 | |

See Notes to Financial Statements.

REGENICIN, INC.
(A Development Stage company)
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

| | Series A Convertible Preferred Stock | | Common Stock | | Discount on Common Stock | Additional Paid-in Capital | Deficit Accumulated During The Development Stage | Treasury Stock | Total |
|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | | | |
| Balances at September 6, 2007 Inception Date) | — | $ — | — | $ — | $ — | — | $ — | $ — | $ — |
| Issuance of common stock for cash | — | — | 73,100,000 | 73,100 | (30,100) | — | — | 43,000 | |
| Net loss | — | — | — | — | — | (4,000) | (4,000) | | |
| Balances at September 0, 2007 | — | — | 73,100,000 | 73,100 | (30,100) | — | (4,000) | 39,000 | |
| Net loss | — | — | — | — | — | — | (44,500) | (44,500) | |
| Balances at September 0, 2008 | — | — | 73,100,000 | 73,100 | (30,100) | — | (48,500) | (5,500) | |
| Net loss | — | — | — | — | — | — | (11,000) | (11,000) | |
| Balances at September 0, 2009 | — | — | 73,100,000 | 73,100 | (30,100) | — | (59,500) | (16,500) | |
| Shares issued for conversion of debt owed to stockholder | — | — | 7,650,000 | 7,650 | (5,400) | — | — | 2,250 | |
| Shares issued under Security Purchase Agreement | — | — | 4,035,524 | 4,036 | 35,500 | 2,093,356 | — | 2,132,892 | |
| Shares issued for conversion of Bridge Notes Payable | — | — | 1,612,903 | 1,613 | — | 748,387 | — | 750,000 | |
| Shares issued for conversion of interest on Bridge Notes Payable | — | — | 7,830 | 8 | — | 3,634 | — | 3,642 | |
| Beneficial conversion feature on Bridge Notes Payable | — | — | — | — | — | 251,214 | — | 251,214 | |
| Forgiveness of officers' loans related to sale of prior business | — | — | — | — | — | 20,250 | — | 20,250 | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Net loss | — | — | — | — | — | — | (935,250) | (935,250) | |
| Balances at September 30, 2010 | — | — | 86,406,257 | 86,407 | — | 3,116,841 | (994,750) | 2,208,498 | |
| Issuance of common stock for cash, net | 623,400 | 623 | 391,150 | 391,773 | | | | | |
| Issuance of common stock for services | 540,000 | 540 | 359,935 | 360,475 | | | | | |
| Issuance of Series A convertible preferred stock | 1,345,000 | 1,345 | 2,679,055 | 2,680,400 | | | | | |
| Shares issued for conversion of amounts owed to a related party | — | — | 666,667 | 667 | 505,333 | — | 506,000 | | |
| Common stock returned to treasury | 4,428 | (4,428) | — | | | | | | |
| Amortization of stock based compensation | 507,251 | 507,251 | | | | | | | |
| Preferred stock dividends | (1,371,110) | (1,371,110) | | | | | | | |
| Net loss | — | — | — | — | — | — | (3,665,582) | (3,665,582) | |
| Balances at September 30, 2011 | 1,345,000 | $ 1,345 | 88,236,324 | $ 88,237 | $ — | 6,192,883 | $ (4,660,332) | $ (4,428) | $ 1,617,705 |

See Notes to Financial Statements.

REGENICIN, INC.
(A Development Stage company)
STATEMENTS OF CASH FLOWS

| | Year Ended September 30, 2011 | Year Ended September 30, 2010 | September 6, 2007 (Inception Date) Through September 30, 2011 |
|---|---|---|---|
| CASH FLOWS FROM OPERATING ACTIVITIES | | | |
| Net loss | $ (3,665,582) | $ (935,250) | $ (4,660,332) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Amortization of beneficial conversion feature | — | 251,214 | 251,214 |
| Stock based compensation | 867,726 | — | 867,726 |
| Changes in operating assets and liabilities | | | |
| Prepaid expenses and other current assets | 12,583 | (25,970) | (13,387) |
| Accounts payable | 517,565 | 221,762 | 739,327 |
| Accrued expenses | 493,156 | 141,627 | 635,783 |
| Net cash used in operating activities | (1,774,552) | (346,617) | (2,179,669) |
| CASH FLOWS FROM INVESTING ACTIVITIES | | | |
| Acquisition of intangible assets | — | (3,007,500) | (3,007,500) |
| Net cash used in investing activities | — | (3,007,500) | (3,007,500) |
| CASH FLOWS FROM FINANCING ACTIVITIES | | | |
| Proceeds from the sale of common stock | 467,550 | 2,502,025 | 3,012,575 |
| Proceeds from the sale of Series A convertible preferred stock | 1,180,000 | — | 1,180,000 |
| Payments of expenses relating to the sale of common stock | (75,777) | (369,133) | (444,910) |
| Payment of expenses relating to the sale of Series A convertible preferred stock | (9,600) | — | (9,600) |
| Proceeds from the issuance of notes payable | 115,000 | 900,000 | 1,015,000 |
| Repayments of notes payable | (235,000) | — | (235,000) |
| Proceeds from advances from related party | 187,211 | 318,789 | 506,000 |
| Proceeds from loans payable | 145,000 | — | 145,000 |
| Proceeds from advances from officer | — | 7,000 | 22,500 |
| Net cash provided by financing activities | 1,774,384 | 3,358,681 | 5,191,565 |
| (DECREASE) INCREASE IN CASH | (168) | 4,564 | 4,396 |
| CASH - BEGINNING OF PERIOD | 4,564 | — | — |
| CASH - END OF PERIOD | $ 4,396 | $ 4,564 | $ 4,396 |
| Supplemental disclosures of cash flow information: | | | |
| Cash paid for interest | $ 6,875 | $ — | |
| Non-cash activities: | | | |
| Preferred stock dividends | $ 1,371,110 | $ — | |
| Issuance of common stock for the conversion of | $ 506,000 | $ — | |

| | | |
|---|---|---|
| amounts owed to related party | | |
| Conversion of notes payable into Series A convertible preferred stock | $ 165,000 | $ — |
| Treasury stock | $ 4,428 | $ — |
| Insurance premiums financed | $ 60,243 | $ — |
| Issuance of common stock for the conversion of bridge notes and accrued interest | $ — | $ 753,642 |
| Forgiveness of amounts owed to former officers relating to the sale of prior business | $ — | $ 20,250 |
| Issuance of common stock for the conversion of amounts owed to officer | $ — | $ 2,250 |

See Notes to Financial Statements.

## NOTE A - THE COMPANY

Windstar, Inc. (the "Company") was incorporated in the state of Nevada on September 6, 2007 and is in the development stage. On July 19, 2010, the Company amended its Articles of Incorporation to change the name of the Company to Regenicin, Inc.

The Company's original business was the development of a purification device. Such business was assigned to the Company's former management in July 2010.

The Company has adopted a new business plan and intends to help develop and commercialize a potentially lifesaving technology by the introduction of tissue-engineered skin substitutes to restore the qualities of healthy human skin for use in the treatment of burns, chronic wounds and a variety of plastic surgery procedures. To this end, we have entered into an agreement with Lonza Walkersville, Inc. ("Lonza") for the exclusive license to use certain proprietary know-how and information necessary to develop and seek approval by the U.S. Food and Drug Administration ("FDA") for the commercial sale of a product known as PermaDerm™.

PermaDerm™ is a tissue-engineered skin substitute prepared from autologous (patient's own) skin cells. It is a combination of cultured epithelium with a collagen-fibroblast implant that produces a skin substitute that contains both epidermal and dermal components. This model has been shown in preclinical studies to generate a functional skin barrier and in clinical studies to promote closure and healing of burns. Critically, the Company believes that self-to-self skin grafts for permanent skin tissue will not be rejected by the immune system of the patient, unlike with porcine or cadaver grafts in which rejection is an important possibility.

The Company's financial statements have been prepared assuming that the Company will continue as a going concern which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has incurred cumulative losses of approximately $4.7 million from inception, expects to incur further losses in the development of its business and has been dependent on funding operations through the issuance of convertible debt and private sale of equity securities. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans include continuing to finance operations through the private or public placement of debt and/or equity securities and the reduction of expenditures. However, no assurance can be given at this time as to whether the Company will be able to achieve these objectives. The financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

On July 19, 2010, the Company declared a stock split of thirty-four (34) to one (1) in which each stockholder was issued thirty-four common shares in exchange for each one common share of their currently issued common stock (the "Split"), which was declared effective by FINRA on August 2, 2010. All share figures and results are reflected on a post-split basis.

## NOTE B - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### Development Stage Activities and Operations:

The Company is in the development stage and has had no revenues. A development stage company is defined as one in which all efforts are devoted substantially to establishing a new business and even if planned principal operations have commenced, revenues are insignificant.

### Intangible assets

Intangible assets, which include purchased licenses, patents and patent rights, are stated at cost and will be amortized using the straight-line method over their useful lives based upon the pattern in which the expected benefits will be realized, or on a straight-line basis, whichever is greater (see Note C). Such amortization will begin once the Company has a saleable product.

We review our intangible assets subject to amortization whenever events or changes in circumstances indicate that the carrying amount of such an asset may not be recoverable. Recoverability of these assets is measured by comparison of their carrying amount to the future undiscounted cash flows the assets are expected to generate. If such assets are considered impaired, the impairment to be recognized is equal to the amount by which the carrying value of the assets exceeds their fair value determined by either a quoted market price, if any, or a value determined by utilizing a discounted cash flow technique. In assessing recoverability, we must make assumptions regarding estimated future cash flows and discount factors. If these estimates or related assumptions change in the future, we may be required to record impairment charges. We did not record any impairment charges in the years ended September 30, 2011.

**Research and development:**

Research and development costs are charged to expense as incurred.

**Loss per share:**

Basic loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding during the period. Diluted earnings (loss) per share give effect to dilutive convertible securities, options, warrants and other potential common stock outstanding during the period; only in periods in which such effect is dilutive. The following securities have been excluded from the calculation of net loss per share, as their effect would be anti-dilutive:

| | Shares of Common Stock Issuable upon Conversion/Exercise as of September 30, | |
|---|---|---|
| | 2011 | 2010 |
| Options | 5,542,688 | -0- |
| Warrants | 2,972,567 | -0- |
| Convertible Preferred Stock | 13,450,000 | -0- |

**Fair Value of Financial Instruments:**

Substantially all of the Company's financial instruments, consisting primarily of accounts payable, accrued expenses and due to stockholders are carried at, or approximate, fair value because of their short-term nature or because they carry market rates of interest.

**Use of Estimates:**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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 expenses during the reporting period. Such estimation includes the selection of assumptions underlying the calculation of the fair value of options. Actual results could differ from those estimates.

**Stock-Based Compensation**

The Company accounts for stock-based compensation in accordance with FASB ASC 718, "*Compensation – Stock Compensation*." Under the fair value recognition provision of the ASC, stock-based compensation cost is estimated at the grant date based on the fair value of the award. The Company estimates the fair value of stock options granted using the Black-Scholes-Merton option pricing model.

The Company accounts for equity instruments issued in exchange for the receipt of goods or services from other than employees in accordance with FASB ASC 505, "*Equity*." Costs are measured at the estimated fair market value of the consideration received or the estimated fair value of the equity Instruments issued, whichever is more reliably measurable. The value of equity instruments issued for consideration other than employee services is determined on the earlier of a performance commitment or completion of performance by the provider of goods or services as defined by ASC 505.

**Income Taxes:**

The Company accounts for income taxes in accordance with accounting guidance now codified as FASB ASC 740, " *Income Taxes*," which requires that the Company recognize deferred tax liabilities and assets based on the differences between the financial statement carrying amounts and the tax bases of assets and liabilities, using enacted tax rates in effect in the years the differences are expected to reverse. Deferred income tax benefit (expense) results from the change in net deferred tax assets or deferred tax liabilities. A valuation allowance is recorded when it is more likely than not that some or all deferred tax assets will not be realized.

The Company has adopted the provisions of FASB ASC 740-10-05 "*Accounting for Uncertainty in Income Taxes*." The ASC clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements. The ASC prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The ASC provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

**Recently Issued Accounting Pronouncements:**

In June 2011, the FASB issued ASU No. 2011-05, "*Comprehensive Income (Topic 220): Presentation of Comprehensive Income (ASU 2011-05)*." ASU 2011-05 provides that an entity that reports items of other comprehensive income has the option to present comprehensive income in either one continuous financial statement or two consecutive financial statements. ASU 2011-05 is effective for annual periods beginning after December 15, 2011. We do not expect ASU 2011-05 to have any impact on our financial position and results of operations.

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

**NOTE C - INTANGIBLES ASSETS**

In July 2010, the Company entered into an agreement with Lonza for the exclusive license to use certain proprietary know-how and information necessary to develop and seek approval by the U.S. Food and Drug Administration ("FDA") for the commercial sale of a product known as PermaDerm™.

The Company paid Lonza $3,000,000 for the exclusive know-how license and assistance to seek approval from the FDA for he commercial sale of PermaDerm™ in the U.S., and later for approval in foreign jurisdictions for commercial sale of PermaDerm™ throughout the world. In conjunction with Lonza, we intend to create and implement a strategy to conduct human clinical trials and to assemble and present the relevant information and data in order to obtain the necessary approvals for PermaDerm™ and possible related products.

See Note J below.

In August 2010, the Company paid $7,500 and obtained the rights to the trademarks PermaDerm® and TempaDerm® from KJR-10 Corp.

**NOTE D – ACCRUED EXPENSES**

Accrued expenses consisted of the following:

| | September 30, 2011 | 2010 |
|---|---|---|
| Registration penalty | $ 250,203 | $ — |
| Salaries and payroll taxes | 286,488 | — |
| Professional fees | 95,450 | 132,735 |
| Accrued dividends | 26,110 | — |
| Interest | — | 1,250 |
| Other | — | 5,000 |
| | $ 658,251 | $ 138,985 |

**NOTE E – LOANS PAYABLE**

In February 2011, certain investors have advanced a total of $85,000. These loans do not bear interest and are due on demand. In June 2011, the Company repaid $75,000 of the advances from the proceeds of the Preferred Stock Offering (see Note I). At September 30, 2011, loans payable totaled $10,000.

**NOTE F – NOTES PAYABLE**

**Insurance Premium Note:**

In August 2011, the Company received a loan totaling $60,243 to fund certain insurance premiums. The note is payable over a nine-month term. The first payment due in September 2011 was made in October 2011. At September 30, 2011, the note balance was $60,243.

**Demand Note:**

On August 2, 2010, the Company issued a $150,000 demand promissory note (the "Demand Note") to NPNC Management, LLC ("NPNC"), a company whose principals also represent the Company as securities counsel. The Demand Note bore interest at 5% per annum.

In March 2011, the Company executed a Promissory Note and Security Agreement (the "Note") with NPNC and three of the Company's directors, Craig Eagle, Joseph Rubinfeld and John Weber for $265,000. Mr. Eagle, Mr. Rubinfeld and Mr. Weber contributed $80,000 and NPNC agreed to contribute the remaining $185,000 of the loan of which $150,000 was previously borrowed and represented by the existing Demand Note and the balance of $35,000 in new funding.

The Note accrued interest at 5% per annum and was secured by the Company's assets. The Note, together with all accrued interest, was due and payable by June 14, 2011. In June 2011, the Note was repaid with interest from the proceeds of the Preferred Stock Offering.

At September 30, 2011 and 2010, the note balance was $0 and $150,000, respectively.

**Bridge Notes:**

In June 2010, July 2010 and August 2010, the Company issued convertible senior secured bridge loan promissory notes (the "Bridge Notes") totaling $750,000. Terms of the Bridge Notes included bearing interest at 5% per annum, which matured on the earlier of six months after the date of the disbursement or the closing of Transactions (as defined). Principal and accrued interest were payable at maturity. The principal and accrued interest were convertible into shares of the Company's common stock by a conversion price equal to 75% of the price per share of common stock sold by the Company in the Security Purchase Agreement discussed below.

On August 20, 2010, the principal of $750,000 and accrued interest totaling $3,642 were converted into 1,620,733 shares of common stock. See Note I – Stockholders' Equity.

At both September 30, 2011 and 2010, the balances due under the notes were $0.

For financial reporting purposes, the Company recorded a discount of $251,514 to reflect the beneficial conversion feature of the Bridge Notes. The discount was being amortized to the date of maturity of the Bridge Notes unless converted earlier. As a result of the conversion of the Bridge Notes, the value of the beneficial conversion feature was expensed in the year ended September 30, 2010.

**NOTE G – RELATED PARTY TRANSACTIONS**

**Officers:**

Siew Mee Fam ("Fam"), our former Chief Executive Officer and Director, along with Sze Yein Wong ("Wong"), another former Director, advanced monies to the Company. Such advances were non-interest bearing and due on demand.

On July 15, 2010, these former officers purchased our air purification device business in exchange for the forgiveness of $20,250 in loans we owed to them. The Company recognized the transaction as an increase of additional paid-in capital.

On July 15, 2010, Randall E. McCoy, the Company's Chief Executive Officer, purchased in a private transaction, an aggregate of 40,800,000 restricted shares of our common stock from Fam and Wong. Under the Stock and Debt Purchase Agreement, Mr. McCoy also purchased $2,250 in debt we owed to Fam and Wong. Following the completion of this transaction, on July 15, 2010, we entered into a Debt Conversion Agreement with Mr. McCoy and agreed to convert the debt purchased by Mr. McCoy in exchange for 7,650,000 shares of our common stock.

At September 30, 2011 and 2010, the Company owed the officers $0 and $0, respectively.

Our principal executive offices are located at in Little Falls, New Jersey. Our headquarters is located in the offices of McCoy Enterprises LLC, an entity controlled by Mr. McCoy. The office is attached to his residence but has its own entrances, restroom and kitchen facilities. No rent is charged.

We also maintain an office in Pennington New Jersey, which is our materials and testing laboratory. This office is owned by Materials Testing Laboratory, and the principal is an employee of our Company.

No rent is charged for either premise.

**The Broadsmoore Group, LLC ("TBG"):**

TBG is a stockholder of the Company. On August 30, 2010, the Company had entered into a finance representation agreement with TBG. TBG was to provide advice to the Company and evaluate relevant transactions the Company may consider.

In addition, TBG advanced monies to the Company. The advances were due on demand and were non-interest bearing. In addition, the Company was utilizing the office space and employees of TBG at no cost.

For the years ended September 30, 2011 and 2010, the Company did not incur any fees to TBG. At September 30, 2011 and 2010, the Company owed TBG $0 and $318,789, respectively.

In fiscal 2011, the Company borrowed additional funds from TBG. Effective December 30, 2010, the Company and TBG signed a settlement agreement by which TBG accepted 666,667 shares of common stock in exchange for all monies owed TBG to date (approximately $506,000). These shares were previously issued as part of the October 28, 2010 offering. In addition, the Company orally agreed to pay a $200,000 success fee to TBG if the Company raises the remaining $3.5 million being offered in its current offering that commenced on October 28, 2010 (see Note I – Stockholders' Equity).

**NOTE H – INCOME TAXES**

At September 30, 2011, the Company had available approximately $3.6 million of net operating loss carry forwards which expire in the years 2028 through 2030.
Significant components of the Company's deferred tax assets at September 30, 2011 and 2010 are as follows:

| | 2011 | 2010 |
|---|---|---|
| Net operating loss carry forwards | $ 1,446,010 | $ 297,272 |
| Stock based compensation | 202,900 | — |
| Accrued expenses | 114,595 | — |
| Total deferred tax assets | 1,763,505 | 297,272 |
| Valuation allowance | (1,763,505) | (297,272) |
| Net deferred tax assets | $ — | $ — |

Due to the uncertainty of their realization, no income tax benefit has been recorded by the Company for these deferred tax assets as valuation allowances have been established for any such benefits. The increase in the valuation allowance was the result of increases in the above stated items.

At September 30, 2011 and 2010, the Company had no material unrecognized tax benefits and no adjustments to liabilities or operations were required. The Company does not expect that its unrecognized tax benefits will materially increase within the next twelve months. We recognize interest and penalties related to uncertain tax positions in general and administrative expense. As of September 30, 2011 and 2010, we have not recorded any provisions for accrued interest and penalties related to uncertain tax positions.

The Company files its federal income tax returns under a statute of limitations. The 2007 through 2010 tax years generally remain subject to examination by federal state tax authorities. The Company has not filed any of its state income tax returns since inception. Due to recurring losses, management believes that once such returns are filed, the Company would incur state minimum tax liabilities that were not deemed material to accrue.

**NOTE I – STOCKHOLDERS' EQUITY**

**Authorized Shares:**

On October 27, 2010, the Company increased the number of authorized shares of common stock from 90,000,000 shares to 200,000,000 by amending our Articles of Incorporation.

**Series A Convertible Preferred Stock:**

In June and July 2011, the Company issued 1,345,000 shares of newly designated Series A Convertible Preferred Stock ("Series A Preferred") and 672,500 Warrants in a private placement, The gross purchase price of the units sold was $1,345,000 of which $105,000 was from loans from certain investors that were converted and $60,000 of cash advances from TBG for the payment of certain operating expenses.

The Company has accounted for the value of the Warrants in accordance with FASB ASC 470, "*Debt*" whereby the Company separately measured the fair value of the Series A Preferred and the Warrant and allocated the total proceeds in accordance with their relative fair value at the time of issuance. The Company valued the warrants at $50,619 utilizing a Black-Scholes option pricing model with the following assumptions: share price: $0.21; exercise price: $0.15; expected volatility: 26.22%; risk-free rate: ..66%; expected term: 3.5 years. The value of the Warrants was recorded as a deemed dividend.

The expected life is the number of years that the Company estimates, based upon history, that the Warrants will be outstanding prior to exercise or forfeiture. Expected life is determined using the "simplified method" permitted by Staff Accounting Bulletin No. 107. The stock volatility factor is based on the Nasdaq Biotechnology Index. The Company did not use the volatility rate for Company Common Stock as the Company Common Stock had not been trading for the sufficient length of time to accurately compute its volatility when these options were issued.

In addition, in accordance with the provisions of ASC 470, the Company allocated a portion of the proceeds received to the beneficial conversion feature, based on the difference between the effective conversion price of the proceeds allocated to the Series A Preferred and the fair value of the underlying common stock on the date the convertible preferred stock was issued. The discount, resulting from the beneficial conversion feature, was recorded as a deemed dividend in the amount of $1,294,381.

The Series A Preferred pay a dividend of 8% per annum on the stated value and the holders do not vote separately as a class (but do vote on an "as-converted" to common stock basis) and have a liquidation preference equal to the stated value of the shares. Each share of Preferred Stock has an initial stated value of $1 and is convertible into shares of the Company's common stock at the rate of 10 for 1. The dividends are cumulative commencing on the issue date whether or not declared. Dividends amounted to $26,110 for the year ended September 30, 2011. At September 30, 2011, dividends payable total $26,110 and are included in accrued expenses.

For the year ended September 30, 2011, dividends and deemed dividends totaled $1,371,110.

**Common Stock Issuances:**

As discussed above, Mr. McCoy purchased $2,250 of debt we owed to Fam and Wong. On July 15, 2010, we entered into a Debt Conversion Agreement with Mr. McCoy and converted the debt purchased in exchange for 7,650,000 shares of our common stock.

On August 16, 2010, we sold 4,035,524 shares of our common stock as part of a Securities Purchase Agreement with certain accredited investors (the "Purchasers") pursuant to the closing of our Private Placement Offering (the "Offering"). The Company received aggregate gross proceeds from the Purchasers of $2,502,025 from the sale of the common stock. Expenses related to the Offering totaled $369,133 and were offset against additional paid-in capital.

Pursuant to a Registration Rights Agreement that accompanies the Securities Purchase Agreement, we agreed to file an initial registration statement covering the resale of the common stock no later than 45 days from the closing of the Offering and to have such registration statement declared effective no later than 180 days from filing of the registration statement. If we do not timely file the registration statement, cause it to be declared effective by the required date, or maintain the filing, then each Purchaser in the offering will be entitled to liquidated damages equal to 1% of the aggregate purchase price paid by such Purchaser for the securities, and an additional 1% for each month that we do not file the registration statement, cause it to be declared effective, of fail to maintain the filing (subject to a maximum penalty of 10% of the aggregate purchase price). The Offering closed on August 16, 2010. The Company has not filed an initial registration statement and began accruing liquidating damages from October 2010. See Registration Penalties discussed below.

On August 16, 2010, the Company converted the Bridge Notes and accrued interest in the aggregate amount of $753,642 into 1,620,733 shares of our common stock.

On October 28, 2010, the Company began offering under a Private Placement Memorandum up to 6,000,000 shares of its common stock at an offering price of $0.75 per share. Offering expenses are estimated to be equal to 10% of the offering price. For the period October 28, 2010 through January 12, 2011, we sold 623,400 shares of common stock and received gross proceeds of $467,550.

Effective November 22, 2010, the Company issued 150,000 shares for consulting services rendered. The shares were valued at $112,500.

Effective December 30, 2010, TBG accepted 666,667 shares of common stock in exchange for all monies owed TBG to date (approximately $506,000).

In February and March 2011, the Company issued 390,000 shares for consulting services rendered. The shares were valued at $247,975.

Stock compensation expense related to the shares totaled $360,475 and $0 for the years ended September 30, 2011 and 2010, respectively.

**Treasury Stock:**

On July 19, 2010, Mr. McCoy agreed to deliver to the Company 4,428,360 shares of common stock beneficially owned by him with instructions that such shares be cancelled and returned to treasury. Such shares were to be returned to offset the potential dilution caused by an equity incentive plan for directors involving the same number of shares that was adopted. Mr. McCoy delivered the shares on January 5, 2011.

**2010 Incentive Plan:**

On December 15, 2010, the board of directors approved the Regenicin, Inc. 2010 Incentive Plan (the "Plan"). The Plan provides for the granting of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock, stock units, performance shares and performance units to our employees, officers, directors and consultants, including incentive stock options, non-qualified stock options, restricted stock, and other benefits. The Plan provides for the issuance of up to 4,428,360 shares of our common stock.

On January 6, 2011, the Company approved the issuance of 885,672 options to each of the four members of the board of directors at an exercise price is $0.62 per share, The options vest over a three-year period and expire on December 22, 2015. The Company valued the options utilizing a Black-Scholes option pricing model with the following assumptions: share price: $0.64; exercise price: $0.62; expected volatility: 26.36%; risk-free rate: 1.11%; expected term: 3.5 years. On May 11, 2011, the terms of the options were amended to allow for immediate vesting.

In addition, the Company approved the issuance of 2,000,000 options to a consultant at an exercise price is $0.46 per share, The options vested immediately and expire in November 2015. The Company valued the options utilizing a Black-Scholes option pricing model with the following assumptions: share price: $0.57; exercise price: $0.46; expected volatility: 27.77%; risk-free rate: 0.72%; expected term: 3 years.

The expected life is the number of years that the Company estimates, based upon history, that options will be outstanding prior to exercise or forfeiture. Expected life is determined using the "simplified method" permitted by Staff Accounting Bulletin No. 107. The stock volatility factor is based on the Nasdaq Biotechnology Index. The Company did not use the volatility rate for Company Common Stock as the Company Common Stock had not been trading for the sufficient length of time to accurately compute its volatility when these options were issued.

Option activity for 2011 and 2010 is summarized as follows:

| | Options | Weighted Average Exercise Price |
|---|---|---|
| Options outstanding, October 1, 2009 | — | $ — |
| Options outstanding, October 1, 2010 | — | — |
| Granted | 5,542,688 | 0.56 |
| Forfeited | — | — |
| Options outstanding, September 30, 2011 | 5,542,688 | $ 0.56 |
| Aggregate intrinsic value | $ — | |

The aggregate intrinsic value was calculated based on the positive difference between the closing market price of the Company's Common Stock and the exercise price of the underlying options.

The following table summarizes information regarding stock options outstanding at September 30, 2011:

| | | Weighted Average Remaining | | Options Exercisable Weighted Average | |
|---|---|---|---|---|---|
| Ranges of prices | Number Outstanding | Contractual Life | Exercise Price | Number Exercisable | Exercise Price |
| $0.46 | 2,000,000 | 5.00 | $ 0.46 | 2,000,000 | $ 0.46 |
| $0.62 | 3,542,688 | 5.00 | 0.62 | 885,672 | 0.62 |
| $0.46-$0.62 | 5,542,688 | 5.00 | $ 0.56 | 2,885,672 | $ 0.51 |



There were no option grants in 2010.

The Company recognized stock compensation expense of $462,961 and $0 for the years ended September 30, 2011 and 2010, respectively. As of September 30, 2011, there was $380,911 of unrecognized compensation cost related to non-vested options granted.

**Warrants:**

In January and March 2011, the Company issued 1,676,667 warrants to various consultants at exercise prices ranging from $0.10 to $1.50 per share. The warrants vest immediately and expire at various times in 2012 and 2016. The Company valued the warrants utilizing a Black-Scholes option pricing model with the following assumptions: share price: $0.39 - $0.64; exercise price: $0.10 - $1.50; expected volatility: 13.35% - 27.56%; risk-free rate: 0.16% - 2.30%; expected term: .5 years - 3 years.

Stock compensation expense related to the warrants totaled $44,290 and $0 for the years ended September 30, 2011 and 2010, respectively.

In March 2011, the Company issued 623,400 warrants to various investors consultants at an exercise price of $0.50 for registration penalties relating to the October 2010 Securities Purchase Agreement (see below). The warrants vest immediately and expire in March 2012. These warrants were deemed to have minimal value utilizing a Black-Scholes option pricing model with the following assumptions: share price: $0.36; exercise price: $0.50; expected volatility: 13.43%; risk-free rate: 0.13%; expected term: .5 years.

The expected life is the number of years that the Company estimates, based upon history, that warrants will be outstanding prior to exercise or forfeiture. Expected life is determined using the “simplified method” permitted by Staff Accounting Bulletin No. 107. The stock volatility factor is based on the Nasdaq Biotechnology Index. The Company did not use the volatility rate for Company Common Stock as the Company Common Stock had not been trading for the sufficient length of time to accurately compute its volatility when these options were issued.

A summary of the warrants outstanding at September 30, 2011 is as follows**:**

| Warrants | | Exercise Price | Expiration Date |
|---|---|---|---|
| 1,500,000 | $ | 0.10 | 2012 |
| 672,500 | $ | 0.15 | 2018 |
| 623,400 | $ | 0.50 | 2012 |
| 10,000 | $ | 0.75 | 2016 |
| 166,667 | $ | 1.50 | 2012-2016 |
| **2,972,567** | | | |

**Registration Penalties:**

On August 16, 2010, we sold 4,035,524 shares of our common stock as part of a Securities Purchase Agreement with certain accredited investors (the “Purchasers”) pursuant to the closing of our Private Placement Offering (the “Offering”).

Pursuant to a Registration Rights Agreement that accompanies the Securities Purchase Agreement, we agreed to file an initial registration statement covering the resale of the common stock no later than 45 days from the closing of the Offering and to have such registration statement declared effective no later than 180 days from filing of the registration statement. If we do not timely file the registration statement, cause it to be declared effective by the required date, or maintain the filing, then each Purchaser in the offering will be entitled to liquidated damages equal to 1% of the aggregate purchase price paid by such Purchaser for the securities, and an additional1% for each month that we do not file the registration statement, cause it to be declared effective, of fail to maintain the filing(subject to a maximum penalty of 10% of the aggregate purchase price). The Offering closed on August 16, 2010. The Company has not filed an initial registration statement and began accruing liquidating damages from October 1, 2010. Registration penalties totaled $250,203 for the year ended September 30, 2011.

On October 28, 2010, the Company began offering under a Private Placement Memorandum up to 6,000,000 shares of its common stock at an offering price of $0.75 per share. Purchasers in this Offering were granted registration rights under the Securities Act with respect to the shares of common stock under the terms of a registration rights agreement (the “Registration Rights Agreement”) executed in connection with the closing of the Offering. Pursuant to the Registration Rights Agreements, the Company will file a Registration Statement with the SEC registering for resale all of such shares within 30 days of the closing of the Offering. The Company further agrees to use its reasonable best efforts to have the Registration Statement declared effective within 120 days of its initial filing date.

In the event the Company is unable to file a Registration Statement covering the Registrable Securities within 30 days following the closing of the Offering, or if the Company is unable to have the Registration Statement declared effective within 120 days of its initial filing date, then as liquidated damages, the Company will grant each stockholder a warrant to purchase the aggregate number of shares purchased in the private offering at a strike price of $0.50 per share. The Offering closed on February 10, 2011. The Company had not filed a registration statement as required and issued 623,400 warrants to the investors in March 2011.

**NOTE J - COMMITMENTS**

**Lonza Transaction:**

The agreement with Lonza contemplates that, upon receipt of the full FDA approval, in the second stage of the transaction, we will execute a Stock Purchase Agreement pursuant to which we will purchase all of the outstanding stock of Cutanogen Corporation ("Cutanogen") from Lonza for an additional purchase price of $2 million. Cutanogen holds certain patents and exclusive licenses to patent rights owned by The Regents of the University of California and the University of Cincinnati and the Shriners Hospital for Children related to the commercialization of PermaDerm™. Upon our acquisition of Cutanogen, we will obtain beneficial use of the Cutanogen Licenses. The beneficial use will extend globally.

When Lonza acquired Cutanogen, it inherited milestone payment obligations to the former Cutanogen shareholders in the total amount of up to $4.8 million. These payments are owed as PermaDerm™ is moved through the FDA approval process. As a result, our deal with Lonza will ultimately include paying those milestones plus the $2 million to Lonza.

**Employment agreements:**

On October 4, 2010, we entered into a written employment agreement with Chris Hadsall. Pursuant to the terms and conditions of the employment agreement:

Mr. Hadsall will serve as Chief Operating Officer of our company for a period of three years;
Mr. Hadsall will earn a base salary of $120,000 for the first 12 months, and will be entitled to increases thereafter as determined by our board of directors;
Mr. Hadsall will be eligible for an annual bonus as determined by our board of directors; and
Mr. Hadsall will be entitled to participate in any employee benefit plans, as established by our board of directors.
Mr. Hadsall signed an agreement to keep certain information confidential and not compete with or solicit from our company for a period of time

On October 4, 2010, we entered into a written employment agreement with Joseph Connell. Pursuant to the terms and conditions of the employment agreement:

Mr. Connell will serve as President of our company for a period of three years;
Mr. Connell will earn a base salary of $250,000 for the first 12 months, and will be entitled to increases thereafter as determined by our board of directors. (He agreed to a reduction in his salary to $125,000 until such time as we achieve a positive net income);
Mr. Connell will be eligible for an annual bonus as determined by our board of directors; and
Mr. Connell will be entitled to participate in any employee benefit plans, as established by our board of directors.

On March 21, 2011, we provided written notice to our Mr. Joseph Connell, that his employment with our company pursuant to his Employment Agreement was terminated for "Cause". Our obligations under the Employment Agreement are limited to the payment of accrued and unpaid salary through the date of his termination and any earned but not yet paid bonus from the prior fiscal year.

**NOTE K – LEGAL PROCEEDINGS**

On February 28, 2011, our board of directors, Mr. Randall McCoy (the Company's CEO), and our company (collectively the "Plaintiffs") filed an amended complaint in the Eighth Judicial District Court of Nevada (Case No. A-11-634976-C) against Joseph Connell, our former President. The Plaintiffs in the amended complaint are requesting declaratory relief from certain allegations Mr. Connell has made in relation to partnership claims with Mr. McCoy, board membership, and stock ownership in the Company. Mr. Connell has requested that the case be removed to federal court in Nevada and has requested that the amended complaint be dismissed for lack of jurisdiction.

On March 11, 2011, Mr. Connell filed a complaint in the Supreme Court of the State of New York (Index No. 103007/11) against Mr. McCoy, the Company, Joseph Rubinfeld, John Weber and Craig Eagle. The complaint alleges, among other things, that Mr. Connell is entitled to 50% of Mr. McCoy's stock in the Company. The complaint requests an accounting from us and requests that we be enjoined from transferring title to Mr. McCoy's shares.

On June 8, 2011, an agreement was reached (the "Agreement") to dismiss the members of the Company's board of directors (excluding Mr.McCoy) and the Company from the case currently pending in the United States District Court for the Southern District of New York. As part of this Agreement, the Company also agreed to dismiss its action originally brought against Mr. Connell in the United States District Court for the District of Nevada. The dispute will continue involving only Mr. Connell and Mr. McCoy as parties in the action pending in the United States District Court for the Southern District of New York. Mr. McCoy has agreed to lock-up 25,000,000 of his personal shares pending the outcome of the case. On November 17, 2011, there was a formal settlement conference before a Magistrate Judge. At that conference, an agreement was reached in principle, with the details to be worked out and a settlement agreement signed on or before January 25, 2012. The settlement agreement has not been signed as of the date of these financial statements.

**NOTE L – SUBSEQUENT EVENTS**

Management has evaluated subsequent events through the date of this filing.

**Promissory Notes:**

On October 12, 2011, the Company issued a $10,000 secured promissory note ("Note 1") to NPNC. The terms of Note 1 include the following:

1. The maturity date is June 14, 2012.
2. Note 1 bears interest at the rate of 5% per annum.
3. Note 1 is secured by the Company's assets.

On December 21, 2011, the Company issued a $150,000 promissory note ("Note 2") to an individual. The terms of Note 2 include the following:

1. The maturity date is June 21, 2012.
2. Note 2 bears interest so that the Company will repay $175,000 on the maturity date. The effective rate is 31.23%.
3. Additional interest of 10% will be charged on any late payments.
4. On the maturity date, the Company will issue one million shares of common stock as additional consideration. The value of these shares will be recorded in the first quarter of fiscal 2012 as financing charges.

**Loan Payable:**

In October 2011, Craig Eagle advanced the Company $35,000. The loan does not bear interest and is due on demand.

**Item 9. Changes In and Disagreements with Accountants on Accounting and Financial Disclosure**

We have previously reported on Changes in and Disagreements with Accountants on Accounting and Financial Disclosure in our Current Report on Form 8-K dated October 20, 2010, which is incorporated by reference, including any amendments thereto.

**Item 9A. Controls and Procedures**

**Disclosure Controls and Procedures**

As required by Rule 13a-15 under the Securities Exchange Act of 1934, we have carried out an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this annual report, being September 30, 2011. This evaluation was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer.

Disclosure controls and procedures are controls and other 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 is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed in our company's reports filed under the Securities Exchange Act of 1934 is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

Based upon that evaluation, including our Chief Executive Officer and Chief Financial Officer, we have concluded that our disclosure controls and procedures were ineffective as of the end of the period covered by this annual report.

**Management's Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934). Management has assessed the effectiveness of our internal control over financial reporting as of September 30, 2010 based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. As a result of this assessment, management concluded that, as of September 30, 2011, our internal control over financial reporting was not effective. Our management identified the following material weaknesses in our internal control over financial reporting, which are indicative of many small companies with small staff: (i) inadequate segregation of duties and effective risk assessment; and (ii) insufficient written policies and procedures for accounting and financial reporting with respect to the requirements and application of both US GAAP and SEC guidelines.

We plan to take steps to enhance and improve the design of our internal control over financial reporting. During the period covered by this annual report on Form 10-K, we have not been able to remediate the material weaknesses identified above. To remediate such weaknesses, we hope to implement the following changes during our fiscal year ending September 30, 2012: (i) appoint additional qualified personnel to address inadequate segregation of duties and ineffective risk management; and (ii) adopt sufficient written policies and procedures for accounting and financial reporting. The remediation efforts set out in (i) and (ii) are largely dependent upon our securing additional financing to cover the costs of implementing the changes required. If we are unsuccessful in securing such funds, remediation efforts may be adversely affected in a material manner.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to an exemption for non-accelerated filers set forth in Section 989G of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

**Remediation of Material Weakness**

We are unable to remedy our controls related to the inadequate segregation of duties and ineffective risk management until we receive financing to hire additional employees. We are currently in the process of hiring an outsourced controller to improve the controls for accounting and financial reporting.

**Limitations on the Effectiveness of Internal Controls**

Our management, including our Chief Executive Officer and our Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting are or will be capable of preventing or detecting all errors or all fraud. Any control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements, due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns may occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risk.

**Item 9B. Other Information**

None

## PART III

**Item 10. Directors, Executive Officers and Corporate Governance**

The following table contains information with respect to our current executive officers and directors:

| Name | Age | Principal Positions With Us |
|---|---|---|
| Randall McCoy | 62 | Chief Executive Officer and Director |
| John J. Weber | 62 | Interim Chief Financial Officer and Director |
| Chris Hadsall | 37 | Chief Operating Officer |
| Joseph Rubinfeld | 79 | Director |
| Craig Eagle | 44 | Director |

***Randall McCoy*** has served as our Chief Executive Officer and director since July 2010. Prior to joining the Company, Mr. McCoy served as President of McCoy Enterprises LLC since its founding in May 2002. Mr. McCoy has more than 37 years of experience in the healthcare industry and has assisted both small and major pharmaceutical/device companies address FDA issues. He served as Laboratory Manager and Instructor at both George Washington University and Temple Medical School, and served as Program Manager at the Stanford Research Institute, Healthcare Division, of the David Sarnoff Research Center. Mr. McCoy has also helped over 225 foreign and domestic companies introduce their FDA regulated drug and medical device products into the US and world market. He currently holds over 30 US and international patents.

***John J. Weber*** has served as our Interim Chief Financial Officer and Director since September 13, 2010. Mr. Weber served as the Executive Vice President of Fujifilm Medical Systems, USA from 2006 until 2009. While at Fujifilm he was responsible for overseeing all corporate activity with the exception of R&D. In previous positions at Fujifilm he served as Senior Vice President of Operations as well as Chief Financial Officer.

Mr. Weber brings 20 years of medical-related corporate, operational and financial management experience to the Company.

***Chris Hadsall*** has served as our Chief Operating Officer since October 4, 2010. Prior to joining the Company, Mr. Hadsall served as an Intelligence Officer for the United States Marine Corps from 1997 to 2006. After serving in the Marine Corps, Mr. Hadsall worked as a Regional Manager for Professional Staffing ABTS from 2006 until 2009. While at Professional Staffing ABTS he guided the day-to-day operations, business development and customer relations for the west coast expansion. From 2007 to the present he maintains his role as the Executive Director of the VET Foundation where he designed, developed and implemented a holistic reintegration program that teaches wounded, ill and injured veterans a life altering transition methodology.

***Dr. Joseph Rubinfeld*** began his career as a research scientist with several pharmaceutical and consumer product companies including Schering Plough and Colgate Palmolive. He served for 12 years at Bristol Myers, where in addition to developing Amoxicillin and Chephadroxil, he was instrumental in licensing their original anti-cancer line of products, including Mitomycin, Etoposide, and Bleomycin. After co-founding Amgen in 1980 and serving as its chief of operations, Dr. Rubinfeld has served as an advisor or Board member to a number of companies including AVI BioPharma and Quark Pharmaceuticals. In 1991 he co-founded Supergen, a drug development company based in Dublin, California, where he served as President and CEO until 2003 and as a member of the Board of Directors until 2005. During that time he oversaw the company's initial public offering and its rise to a multi-billion dollar market capitalization. Management believes his wealth of experience in biotech and big pharma will be instrumental for Regenicin as it transitions to commercialization.

***Dr. Craig Eagle*** was appointed to our board of directors on September 7, 2010. He currently serves as Vice President of Strategic Alliances and Partnerships for the Oncology business unit at Pfizer Inc. Dr. Eagle joined Pfizer Australia in 2001 as part of the medical group and has held various positions and over the years including his appointment in 2003 as the worldwide leader for development of Celecoxib in oncology to oversee the global research program. In 2007, he became head of the oncology therapeutic area medical group for Pfizer, including the United States oncology business.

We acknowledge Dr. Eagle's wealth of experience in pharmaceutical product development as well as his extensive experience in forming strategic alliances and partnerships and believe he will provide us with critical guidance as we seek to maximize the commercialization potential of our products.

**Term of Office**

Our directors are appointed for a one-year term to hold office until the next annual general meeting of our shareholders or until removed from office in accordance with our bylaws. Our officers are appointed by our board of directors and hold office until removed by the board.

**Family Relationships**

There are no family relationships between or among the directors, executive officers or persons nominated or chosen by us to become directors or executive officers.

**Involvement in Certain Legal Proceedings**

To the best of our knowledge, during the past ten years, none of the following occurred with respect to a present or former director, executive officer, or employee: (1) any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time; (2) any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses); (3) being subject to any order, judgment or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his or her involvement in any type of business, securities or banking activities; and (4) being found by a court of competent jurisdiction (in a civil action), the SEC or the Commodities Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended or vacated.

**Committees of the Board**

Our company currently does not have nominating, compensation or audit committees or committees performing similar functions nor does our company have a written nominating, compensation or audit committee charter. Our directors believe that it is not necessary to have such committees, at this time, because the functions of such committees can be adequately performed by the board of directors.



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Our company does not have any defined policy or procedural requirements for shareholders to submit recommendations or nominations for directors. The board of directors believes that, given the stage of our development, a specific nominating policy would be premature and of little assistance until our business operations develop to a more advanced level. Our company does not currently have any specific or minimum criteria for the election of nominees to the board of directors and we do not have any specific process or procedure for evaluating such nominees. The board of directors will assess all candidates, whether submitted by management or shareholders, and make recommendations for election or appointment.

A shareholder who wishes to communicate with our board of directors may do so by directing a written request addressed to our CEO and director, Randall McCoy, at the address appearing on the first page of this annual report.

**Code of Ethics**

We have adopted a Code of Ethics that applies our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the Code of Ethics is attached to our Annual Report on Form 10-K for the year ended September 30, 2011 as Exhibit 14.1.



**Item 11. Executive Compensation**

The table below summarizes all compensation awarded to, earned by, or paid to our officers for all services rendered in all capacities to us for our fiscal years ended September 30, 2010 and 2011.

SUMMARY COMPENSATION TABLE

| Name and principal position | Year | Salary ($) | Bonus ($) | Stock Awards ($) | Option Awards ($) | Non-Equity Incentive Plan Compensation ($) | Nonqualified Deferred Compensation Earnings ($) | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|---|---|---|---|---|
| **Siew Mee Fam** Former President, Chief Executive Officer, Principal Executive Officer, Chief Financial Officer, Principal Financial Officer, Principal Accounting Officer and Director | 2010 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2011 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Randall McCoy** Chief Executive Officer, Principal Executive Officer and Director | 2010 | $30,000 | 0 | 0 | 0 | 0 | 0 | 0 | $30,000 |
| | 2011 | $125,000[1] | 0 | 0 | $31,743[3] | 0 | 0 | 0 | $156,743 |
| **Joseph Connell** Former President | 2010 | $30,000 | 0 | 0 | 0 | 0 | 0 | 0 | $30,000 |
| | 2011 | $41,830 | 0 | 0 | 0 | 0 | 0 | 0 | $41,830 |
| **John J. Weber** Interim Chief Financial Officer, and Director | 2010 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2011 | 0 | 0 | 0 | $31,743[3] | 0 | 0 | 0 | $31,743 |
| **Chris Hadsall** Chief Operating Officer | 2010 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2011 | $120,000[2] | 0 | 0 | 0 | 0 | 0 | 0 | $120,000 |

[1] Of the $125,000 in salary to Mr. McCoy, $60,000 remains unpaid as accrued compensation.
[2] Of the $120,000 in salary to Mr. Hadsall, $55,000 remains unpaid as accrued compensation.
[3] Reflects the aggregate grant date fair value computed in accordance with FASB ASC 718.

**Narrative Disclosure to Summary Compensation Table**

***Randall McCoy***

On July 16, 2010, we entered into an employment agreement with Mr. Randall McCoy. The employment agreement has a three-year term that automatically extends in three-year increments unless notice of non-renewal is given by either party at least ninety (90) days prior to the expiration of the then current term.

The July 16, 2010 employment agreement provided for an initial annual base salary of $250,000. Under an addendum to the employment agreement, however, dated August 2, 2010, Mr. McCoy will earn an annual base salary of $125,000 until such time as we achieve a positive net income for the preceding calendar quarter as determined in accordance with GAAP and reported in our financial statements filed with the Securities and Exchange Commission under the Securities and Exchange Act of 1934, as amended. Immediately upon our attaining such positive net income, Mr. McCoy's annual base salary will be increased to $250,000 as stated in the July 16, 2010 employment agreement.

The annual base salary will be reviewed each year by our board of directors (or compensation committee, if we then have one), but cannot be decreased from the amount in effect in the previous year. Pursuant to the employment agreement, Mr. McCoy is eligible for an annual bonus determined by our board of directors (or compensation committee, if any). The employment agreement also provides that Mr. McCoy is eligible to participate in our equity incentive plans and other employee benefit programs.

Mr. McCoy's employment agreement imposes on him post-termination non-competition, non-solicitation and confidentiality obligations. Under the agreement, he agrees not to compete with our business in the United States, subject to certain limited exceptions, for a period of one year after termination of his employment. Mr. McCoy further agrees, for a period of one year after termination of his employment, to refrain from (i) soliciting, inducing, encouraging or attempting to induce or encourage any employee, contractor or consultant of the Company to terminate his or her employment or relationship with Company, or to breach any other obligation to Company; and (ii) soliciting, interfering with, disrupting, altering or attempting to disrupt or alter the relationship, contractual or otherwise, between the Company and any other person including, without limitation, any consultant, contractor, customer, potential customer, or supplier of the Company. He also agrees to maintain the confidentiality of all confidential or proprietary information of our company, and assign to us any inventions which pertain to or relate to our business or any of the work or businesses carried on by us that are discovered, conceived, reduced to practice, developed, made or produced by him during and as a result of his employment.



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The employment agreement provides for payments and benefits upon termination of employment in addition to those previously accrued. If Mr. McCoy is terminated due to death, the salary payable to Mr. McCoy thereunder (in addition to items previously accrued, but excluding medical plan and other benefits) shall continue to be paid at the then current rate for three (3) months after the termination of employment in accordance with normal Company payroll practices. In addition, any bonuses actually earned prior to the termination (including, as reasonably determined by the Board of Directors or its Compensation Committee, a pro-rated amount of any annual bonus for the portion of the fiscal year during which termination takes place) shall be paid to Mr. McCoy.

In the event of the termination of Mr. McCoy's employment due to disability, the salary payable thereunder (inclusive of paid medical plan then in effect and available, if any) shall continue to be paid at the then current rate for three (3) months after the termination of employment in accordance with normal Company payroll practices; provided, however, that the Company may deduct from such payments the amount of any and all disability insurance benefits paid during such three-month period with respect to Mr. McCoy that were paid for by the Company during any period for which payment was made by the Company during the term of the and prior to the termination. In addition, any bonuses actually earned prior to the termination (including, as reasonably determined by the Board of Directors or its Compensation Committee, a pro-rated amount of any annual bonus for the portion of the fiscal year during which termination takes place) which shall be paid to Mr. McCoy.

***Other Employees***

On October 4, 2010, we entered into a written employment agreement with Chris Hadsall. Pursuant to the terms and conditions of the employment agreement:

- Mr. Hadsall will serve as Chief Operating Officer of our company for a period of three years;
- Mr. Hadsall will earn a base salary of $120,000 for the first 12 months, and will be entitled to increases thereafter as determined by our board of directors;
- Mr. Hadsall will be eligible for an annual bonus as determined by our board of directors; and
- Mr. Hadsall will be entitled to participate in any employee benefit plans, as established by our board of directors.

On October 4, 2010, we entered into a written employment agreement with Joseph Connell. As of March 21, 2011, Mr. Connell is not employed with our company.

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

The table below summarizes all unexercised options, stock that has not vested, and equity incentive plan awards for each named executive officer as of September 30, 2011.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

| | OPTION AWARDS | | | | | STOCK AWARDS | | | |
|---|---|---|---|---|---|---|---|---|---|
| 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 ($) | Option Expiration Date | Number of Shares or Units of Stock That Have Not Vested(#) | Market Value of Shares or Units of Stock That Have Not Vested ($) | Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#) | Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested(#) |
| **Randall McCoy** | 885,672 | - | - | $0.62 | December 22, 2015 | - | - | - | - |
| **Craig Eagle** | 885,672 | - | - | $0.62 | December 22, 2015 | - | - | - | - |
| **John J. Weber** | 885,672 | - | - | $0.62 | December 22, 2015 | - | - | - | - |
| **Joseph Rubinfeld** | 885,672 | - | - | $0.62 | December 22, 2015 | - | - | - | - |

**Director Compensation**

The table below summarizes all compensation of our directors as of September 30, 2011.

DIRECTOR COMPENSATION

| Name | Fees Earned or Paid in Cash ($) | Stock Awards ($) | Option Awards ($) | Non-Equity Incentive Plan Compensation ($) | Non-Qualified Deferred Compensation Earnings ($) | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|---|---|---|
| **Dr. Joseph Rubinfeld** | - | - | $31,743[(1)] | - | - | - | $31,743 |
| **Dr. Craig Eagle** | - | - | $31,743[(1)] | - | - | - | $31,743 |

[(1)] Reflects the aggregate grant date fair value computed in accordance with FASB ASC 718.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The following table sets forth, as of January 5, 2012, certain information as to shares of our common stock owned by (i) each person known by us to beneficially own more than 5% of our outstanding common stock, (ii) each of our directors, and (iii) all of our executive officers and directors as a group.

Unless otherwise indicated below, to our knowledge, all persons listed below have sole voting and investment power with respect to their shares of Common Stock, except to the extent authority is shared by spouses under applicable law. Unless otherwise indicated below, each entity or person listed below maintains an address of 10 High Court, Little Falls, NJ 07424.

The number of shares beneficially owned by each stockholder is determined under rules promulgated by the SEC. The information is not necessarily indicative of beneficial ownership for any other purpose. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting or investment power and any shares as to which the individual or entity has the right to acquire beneficial ownership within 60 days through the exercise of any stock option, warrant or other right. The inclusion in the following table of those shares, however, does not constitute an admission that the named stockholder is a direct or indirect beneficial owner.

| **Beneficial owner** | **Number of shares beneficially owned** (1) | **Percentage Owned** (2) |
|---|---|---|
| **Oficers and Directors** | | |
| Randall McCoy | 33,727,313(3) | 39.80% |
| John J. Weber | 935,672(4) | 1.10% |
| Chris Hadsall | 0 | * |
| Joseph Rubinfeld | 1,935,672(5) | 2.29% |
| Craig Eagle | 935,672(6) | 1.10% |
| Officers and Directors collectively | 37,514,329(7) | 42.95% |
| | | |
| **5 Percent Shareholders** | | |
| The Broadsmoore Group, LLC<br>560 Lexington Ave., 16th Fl.<br>New York, NY 10022 | 9,223,770(8) | 10.56% |
| PDA Associates LLC<br>560 Lexington Ave., 16th Fl.<br>New York, NY 10022 | 7,770,000(9) | 9.23% |
| Officers, directors and 5 percent shareholders collectively | 54,508,099(10) | 59.74% |

* Less than 1%

(1) Unless otherwise indicated, each person or entity named in the table has sole voting power and investment power (or shares that power with that person's spouse) with respect to all shares of common stock listed as owned by that person or entity.

(2) A total of 83,807,964 shares of the Company's common stock are considered to be outstanding pursuant to Rule 13d-3(d)(1) under the Securities Exchange Act of 1934.

(3) Includes 32,821,641 shares of common stock held in his name and options to purchase 885,672 shares of common stock.

(4) Includes 50,000 shares of common stock held in his name and options to purchase 885,672 shares of common stock,

(5) Includes 1,050,000 shares of common stock held in his name and options to purchase 885,672 shares of common stock

(6) Includes 50,000 shares of common stock held in his name and options to purchase 885,672 shares of common stock,

(7) Includes 33,971,641 shares of common stock, options to purchase 3,542,688 shares of common stock and shares of Series A Convertible Preferred Stock convertible into 3,350,000 shares of common stock,

(8) Includes 5,706,270 shares of common stock held in its name, warrants to purchase 167,500 shares of common stock and shares of Series A Convertible Preferred Stock convertible into 3,350,000 shares of common stock,

(9) Includes 7,400,000 shares of common stock held in its name and warrants to purchase 370,000 shares of common stock,

(10) Includes 47,077,911 shares of common stock, warrants to purchase 537,500 shares of common stock, options to purchase 3,542,688 shares of common stock and shares of Series A Convertible Preferred Stock convertible into 3,350,000 shares of common stock

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

Other than the transactions described below and under the heading "Executive Compensation" (or with respect to which such information is omitted in accordance with SEC regulations), since October 1, 2010 there have not been, and there is not currently proposed, any transaction or series of similar transactions to which we were or will be a participant in which the amount involved exceeded or will exceed the lesser of $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years, and in which any director, executive officer, holder of 5% or more of any class of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest.

The Broadsmoore Group, LLC ("TBG") is a stockholder of our company that had previously loaned us money. Effective December 30, 2010, we and TBG signed a settlement agreement by which we issued TBG 666,667 shares of common stock in exchange for all monies owed TBG to date (approximately $506,000).

In October 2011, Mr. Craig Eagle, a member of our board of directors, loaned us $35,000 for working capital. The loan is does not bear interest and is due on demand.

**Item 14. Principal Accounting Fees and Services**

We do not have an audit committee. Our Board of Directors pre-approves all services, including both audit and non-audit services, provided by our independent accountants. For audit services, each year the independent auditor provides our Board of Directors with an engagement letter outlining the scope of the audit services proposed to be performed during the year, which must be formally accepted by the Board of Directors before the audit commences. The independent auditor also submits an audit services fee proposal, which also must be approved by the Board of Directors before the audit commences.

From inception through November 17, 2010, our principal independent auditor was Maddox Ungar Silberstein, PLLC ("Maddox"); and thereafter, we engaged Rotenberg Meril Solomon Bertiger & Guttilla, P.C. ("RMSBG") for the audit of the years ended September 30, 2011 and 2010.

.Below is the table of Audit Fees billed by our auditors in connection with the audits of the Company's annual financial statements for the years ended:

| Financial Statements for the Year Ended September 30 | Audit Services | Audit Related Fees | Tax Fees | Other Fees |
|---|---|---|---|---|
| 2011 | $54,500 | $1,002 | $0 | $0 |
| 2010 | $60,893 | $0 | $0 | $0 |

## PART IV

**Item 15. Exhibits, Financial Statements Schedules**

*(a) Financial Statements and Schedules*

The following financial statements and schedules listed below are included in this Form 10-K.

Financial Statements (See Item 8)

*(b) Exhibits*

| Exhibit Number | Description |
|---|---|
| 3.1 | Articles of Incorporation, as amended (1) |
| 3.2 | Bylaws, as amended (1) |
| 10.4 | Know-How License and Stock Purchase Agreement (2) |
| 14.1 | Code of Ethics (3) |
| 31.1 | Certification of Chief Executive Officer pursuant to Securities Exchange Act Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 31.2 | Certification of Chief Financial Officer pursuant to Securities Exchange Act Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 32.1 | Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |

(1) Incorporated by reference to the Registration Statement on Form SB-2 filed on October 25, 2006.
(2) Incorporated by reference to the Current Report on Form 8-K/A filed on April 27, 2011.
(3) Incorporated by reference to the Annual Report on Form 10-K filed on January 13, 2011.

**SIGNATURES**

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Regenicin, Inc.

By: /s/ Randall McCoy
Randall McCoy
President, Chief Executive Officer, Principal Executive Officer,
and Director

January 13, 2012

In accordance with Section 13 or 15(d) of the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

By: /s/ Randall McCoy
Randall McCoy
President, Chief Executive Officer, Principal Executive Officer,
and Director

January 13, 2012

By: /s/ John J. Weber
John J. Weber
Interim CFO and Director

January 13, 2012

By: /s/ Joseph Rubinfeld
Dr. Joseph Rubinfeld
Director

January 13, 2012

By: /s/ Craig Eagle
Dr. Craig Eagle
Director

January 13, 2012