Intellicell Biosciences, Inc.
Form 8-K/A
August 11, 2011

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

FORM 8-K/A
(Amendment No. 3)

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported) June 3, 2011

Media Exchange Group, Inc.
(Exact Name of Registrant as Specified in Charter)

Nevada	333-49388	91-1966948
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

30 East 76 th Street, 6 th Floor, New York, New York	10021
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (212) 249-3050

101 Church Street, Suite 14, Los Gatos, California 95030
(Former Name or Former Address, if Changed Since Last Report)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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CURRENT REPORT ON FORM 8-K/A

MEDIA EXCHANGE GROUP, INC.

JUNE 3, 2011

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Explanatory Note

We are filing this Amendment No. 3 to our Current Report on Form 8-K (the "Amendment") as originally filed with the Securities and Exchange Commission (the "SEC") on June 7, 2011 (the "Original Filing") as amended on June 17, 2011 (the "First Amendment") and July 26, 2011 (the "Second Amendment" and together with the First Amendment, the "Amended Filings") to amend and restate the filing in its entirety and to include a revised audit opinion of Rosen Seymour Shapss Martin & Company LLP in Exhibit 99.2. Except as described above, no other information in the Original Filing and the Amended Filings has been updated and this Amendment continues to speak as of the date of the Original Filing and the Amended Filings. Other events occurring after the filing of the Original Filing, the Amended Filings or other disclosure necessary to reflect subsequent events will be addressed in other reports filed with or
furnished to the SEC subsequent to the date of the filing of the Original Filing and the Amended Filings.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains some forward-looking statements. Forward-looking statements give our current expectations or forecasts of future events. You can identify these statements by the fact that they do not relate strictly to historical or current facts. Forward-looking statements include statements regarding, among other things, (a) our projected sales, profitability and cash flows, (b) our growth strategies, (c) anticipated trends in our industries, (d) our future financing plans and (e) our anticipated needs for working capital. They are generally identifiable by use of the words "may," "will," "should," "anticipate," "estimate," "plans," "potential," "projects," "continuing," "ongoing," "expects," "management believes," "we believe," "we intend" or the negative of these words or other variations on these words or comparable terminology. These statements may be found under "Management's Discussion and Analysis of Financial Condition and Plan of Operation" and "Business," as well as in this report generally. In particular, these include statements relating to future actions, prospective product approvals, future performance or results of current and anticipated sales efforts, expenses, the outcome of contingencies such as legal proceedings, and financial results.

Any or all of our forward-looking statements in this report may turn out to be inaccurate, as a result of inaccurate assumptions we might make or known or unknown risks or uncertainties. Therefore, although we believe that these statements are based upon reasonable assumptions, including projections of operating margins, earnings, cash flows, working capital, capital expenditures and other projections, no forward-looking statement can be guaranteed. Our forward-looking statements are not guarantees of future performance, and actual results or developments may differ materially from the expectations they express. You should not place undue reliance on these forward-looking statements.

Information regarding market and industry statistics contained in this report is included based on information available to us which we believe is accurate. We have not reviewed or included data from all sources, and cannot assure stockholders of the accuracy or completeness of this data. Forecasts and other forward-looking information obtained from these sources are subject to these qualifications and the additional uncertainties accompanying any estimates of future market size, revenue and market acceptance of products and services.

These statements also represent our estimates and assumptions only as of the date that they were made and we expressly disclaim any duty to provide updates to them or the estimates and assumptions associated with them after the date of this filing to reflect events or changes in circumstances or changes in expectations or the occurrence of anticipated events.

We undertake no obligation to publicly update any predictive statement in this report, whether as a result of new information, future events or otherwise. You are advised, however, to consult any additional disclosures we make in reports we file with the SEC on Form 10-K, Form 10-Q and Form 8-K.

Item 1.01 Entry into a Material Definitive Agreement.

On April 27, 2011, Media Exchange Group, Inc. (the "Company") entered into an Agreement and Plan of Merger by and among the Company, Intellicell Acquisition Corp., a New York corporation and a wholly-owned subsidiary of MEG ("Merger Sub") and IntelliCell Biosciences, Inc., a New York corporation ("IntelliCell"). Thereafter, on June 3, 2011, the parties entered into an Amended and Restated Agreement and Plan of Merger (the Merger Agreement, as amended and restated is hereinafter referred to as the "(the "Merger Agreement"). Pursuant to the Merger Agreement, IntelliCell merged with and into the Merger Sub with IntelliCell continuing as the surviving corporation (the "Merger"). As consideration for the Merger, the holders of the an aggregate of 7,975,768 shares of IntelliCell's common stock exchanged their shares of common stock for an aggregate of 15,476,978 shares of the Company's common stock and Steven Victor, the principal shareholder of IntelliCell, exchanged an aggregate of 10,575,482 shares of IntelliCell's common stock for an aggregate of 20,521 shares of the Company's series B preferred stock, based upon an effective exchange rate of 1.94 shares of the Company for each share of Intellicell common stock held (the "Transaction"). Each share of series B preferred stock shall be convertible into 1,000 shares of the Company's common stock. In addition, the holders of the series B preferred stock shall be entitled to notice of stockholders' meeting and to vote as a single class with the holders of the Common Stock upon any matter submitted to the stockholders for a vote, and shall be entitled to such number of votes as shall equal the product of (a) the number of shares of Common Stock into which the series B preferred stock is convertible into on the record date of such vote multiplied by (b) ten (10). The Merger Agreement contains customary terms and conditions for a transaction of this type, including representations, warranties and covenants, as well as provisions describing the merger consideration, the process of exchanging the consideration and the effect of the Merger. The closing of the Merger took place on June 3, 2011 (the "Closing Date").

In addition to the foregoing, in accordance with the Merger Agreement, all outstanding convertible notes issued by Intellicell (the "IntelliCell Notes") and warrants issued by Intellicell (the "IntelliCell Warrants") shall entitle the holder to convert or exercise, as the case may be, into and receive the same number of shares of Company common stock as the holder of such Intellicell Notes and Intellicell Warrants would have been entitled to receive pursuant to the Merger had such holder exercised such Intellicell Notes and Intellicell Warrants in full immediately prior to the closing of the Merger. Thus, there are an aggregate of $1,385,000 of Intellicell Notes outstanding which are convertible into an aggregate of 1,573,864 shares of common stock of the Company (at a conversion price of $0.88) and warrants to purchase an aggregate of 3,076,189 shares of common stock of the Company (at an exercise price of $0.88).

Following the Merger, the Company will be changing its name to IntelliCell Biosciences, Inc., and our trading symbol is expected to be changed as well. As a result of the Merger, IntelliCell became our wholly-owned subsidiary, with Intellicell's former shareholders acquiring a majority of the outstanding shares of our common stock, as well as all of the shares of our series B preferred stock.

A copy of the press release announcing the Merger is attached hereto as Exhibit 99.1

Merger Agreement

Pursuant to the Merger Agreement, at closing, we issued an aggregate of 15,476,978 shares of common stock to the holders of an aggregate of 7,975,768 of IntelliCell's common stock, and 20,521 shares of the series B preferred stock to Dr. Steven Victor, the principal shareholder of Intellicell, in exchange for an aggregate of 10,575,482 shares of IntelliCell's common stock, in exchange for 100% of the issued and outstanding shares of Intellicell common stock. The consideration issued in the Merger was determined as a result of arm's-length negotiations between the parties.

In addition to the foregoing, in accordance with the Merger Agreement, all outstanding convertible notes issued by Intellicell (the "IntelliCell Notes") and warrants issued by Intellicell (the "IntelliCell Warrants") shall entitle the holder to convert or exercise, as the case may be, into and receive the same number of shares of Company common stock as the holder of such Intellicell Notes and Intellicell Warrants would have been entitled to receive pursuant to the Merger had such holder exercised such Intellicell Notes and Intellicell Warrants in full immediately prior to the closing of the Merger. Thus, there are an aggregate of $1,385,000 of Intellicell Notes outstanding which are convertible into an aggregate of 1,573,864 shares of common stock of the Company (at a conversion price of $0.88) and warrants to purchase an aggregate of 3,076,189 shares of common stock of the Company (at an exercise price of $0.88).

The shares of our common stock and series B preferred stock issued to former holders of Intellicell's common stock in connection with the Merger were not registered under the Securities Act of 1933, as amended (the "Securities Act") in reliance upon the exemption from registration provided by Section 4(2) of that Act and Regulation D promulgated under that section, which exempts transactions by an issuer not involving any public offering. These securities may not be offered or sold in the United States absent registration or an applicable exemption from the registration requirements. Certificates representing these securities contain a legend stating the same.

In connection with the Merger, the Company's former controlling shareholder entered into a return to treasury agreement pursuant to which he agreed to return to the Company for cancellation all of shares of series A preferred stock of the Company that had previously been issued to him (150,000 shares). The Company then cancelled those shares at the closing of the Merger.

Changes Resulting from the Transaction

We intend to carry on Intellicell's business as our primary line of business. Intellicell is headquartered in New York, New York, and is focused on the expanding regenerative medical markets using adipose stromal vascular fraction. We have relocated our principal executive offices to those of IntelliCell at 30 East 76th Street, 6th Floor, New York, New York. Our telephone number is (212) 249-3050, and our website is located at www.intellicell.com. The contents of IntelliCell's website are not part of this report and should not be relied upon with respect thereto.

Expansion of Board of Directors; Management

In connection with the Merger, on June 3, 2011, Joseph R. Cellura resigned as our chief executive officer, president and director and Rachael Baer resigned as general counsel, secretary and treasurer, effective immediately, and we appointed (i) Steven Victor MD as our chief executive officer, president, secretary, treasurer and director and (ii) Leonard Mazur and Stuart Goldfarb as members of our board of directors.

All directors hold office until the next annual meeting of stockholders and the election and qualification of their successors. Officers are elected annually by the board of directors and serve at the discretion of the board.

Accounting Treatment; Change of Control

The Merger is being accounted for as a "reverse acquisition," since the shareholders of IntelliCell own a majority of the outstanding shares of our common stock immediately following the Merger. IntelliCell is deemed to be the acquirer in the Merger and, consequently, the assets and liabilities and the historical operations that will be reflected in the financial statements will be those of IntelliCell and will be recorded at the historical cost basis of IntelliCell. Except as described in the previous paragraphs, no arrangements or understandings exist among present or former controlling stockholders with respect to the election of members of our board of directors and, to our knowledge, no other arrangements exist that might result in a change of control of our company. Further, as a result of the issuance of the 15,476,978 shares of our common stock and 20,521 shares of series B preferred stock (which are convertible into an aggregate of 20,521,000 shares of common stock) in the Merger, and cancellation of other shares, a change in control of our company occurred on the date of the consummation of the Merger. We will continue to be a "smaller reporting company," as defined under the Exchange Act following the Merger.

Debt Conversions and Settlements

Prior to the consummation of the Merger, the Company entered into agreements the holders of an aggregate of $1,619,606 of indebtedness to the Company, comprised of accrued compensation in the amount of $1,201,551, promissory notes in the principal amount of $263,707 plus accrued interest of $9.398 less unamortized debt discounts of $83,264 and accrued expenses totaling $228,414 (the "Series C Debt"), which included $,1,201,551 of accrued compensation, $128,047 of notes payable held or made by affiliates of the Company, pursuant to which such persons agreed to settle and compromise such Series C Debt in exchange for the issuance of an aggregate of 12,123 shares of series C preferred stock. Each share of series C preferred stock shall be convertible into 1,000 shares of the Company's common stock. Certain holders of the Company's series C preferred stock have contractually agreed to restrict their ability to convert the series C preferred stock such that the number of shares of the Company common stock held by each of holder and its affiliates after such conversion shall not exceed 4.99% of the Company's then issued and outstanding shares of common stock.

Furthermore, prior to the consummation of the Merger, the Company entered into agreements with the holders of an aggregate of $250,000 of accrued compensation, pursuant to which such persons agreed to forgive all amounts owed

to the Company.

In addition, prior to the consummation of the Merger, the Company entered into agreements with the holders of (i) an aggregate of $86,000 of notes and $50,000 in accrued expenses pursuant to which such persons agreed to settle and compromise such debt in exchange for the issuance of an aggregate of 262,500 shares of common stock, and (ii) an aggregate of $375,000 of notes of the Company pursuant to which such person agreed to amend such note to make it convertible into an aggregate of 187,500 shares of common stock of the Company (based upon a conversion price of $2.00 per share). In addition, the Company issued an aggregate of 1,000,000 shares of common stock pursuant to a settlement and compromise with a debt holder of the Company.

Lock-Up Agreements and Other Restrictions

In connection with the Merger, former shareholders who now hold in the aggregate 12,123 shares of our series C preferred stock, entered into lock-up agreements with us. The lock-up agreements provide that their shares may not be, directly or indirectly, publicly sold, subject to a contract for sale or otherwise transferred for a period ending on until August 31, 2011. Certain holders of the Company's series C preferred stock have contractually agreed to restrict their ability to convert the series C preferred stock such that the number of shares of the Company common stock held by each of holder and its affiliates after such conversion shall not exceed 4.99% of the Company's then issued and outstanding shares of common stock.

The foregoing information is a summary of the agreements involved in the transactions described above, is not complete, and is qualified in its entirety by reference to the full text of such agreements, a copy of which are attached as an exhibit to this Current Report on Form 8-K. Readers should review such agreement for a complete understanding of the terms and conditions associated with this transaction.

Asset Purchase Agreement with Consorteum Holdings, Inc.

Following completion of the Merger, on June 6, 2011, the Company entered into an asset purchase agreement (the "Consorteum Purchase Agreement") with Consorteum Holdings, Inc. ("Consorteum") pursuant to which the Company has agreed to sell, transfer and assign to Consorteum, and Consorteum has agreed to purchase from the Company, all of the Company rights, title and interests to, and agreements relating to, its digital trading card business and platform as well as all other intangible assets of the business in exchange for Consorteum assuming an aggregate principal amount of $1,864,152 of indebtedness of the Company in accordance with the terms of that certain assignment and assumption agreement executed on June 6, 2011. Such rights include, but are not limited to, the Company's name, phone number and listing, goodwill and other intangible assets (including its rights to any intellectual property or proprietary technology), as well as the company's rights under certain licensing agreements.

On June 6, 2011, the Company and Consorteum entered into an amendment agreement (the "Amendment Agreement") to the Consorteum Purchase Agreement pursuant to which the parties agreed, among other things, that the obligations of the Parties to consummate the transactions contemplated by the Purchase Agreement is subject to (i) the approval of the Board of Directors of each of the parties, and (ii) the completion of the assignment of the Assumed Liabilities (including receipt of all the necessary consents of the holders of all outstanding indebtedness of the Buyer).

Assuming that the transactions contemplated by the Consorteum Purchase Agreement and the Amendment Agreement are consummated, the Company's only remaining outstanding notes consist of an aggregate of $750,000 of notes of the Company, $375,000 of which has been amended and is convertible into an aggregate of 187,500 shares of common stock of the Company (based upon a conversion price of $2.00 per share) and the remaining $375,000 is not convertible.

Item 2.01 Completion of Acquisition or Disposition of Assets.

Merger Agreement

On April 27, 2011, the Company entered into an Agreement and Plan of Merger by and among the Company, Merger Sub and IntelliCell. Thereafter, on June 3, 2011, the parties entered into an Amended and Restated Agreement and Plan of Merger (the Merger Agreement, as amended and restated is hereinafter referred to as the "(the "Merger Agreement"). Pursuant to the Merger Agreement, IntelliCell merged with and into the Merger Sub with IntelliCell continuing as the surviving corporation.

Pursuant to the Merger Agreement, at closing, we issued an aggregate of 15,476,978 shares of common stock to the holders of an aggregate of 7,975,768 of IntelliCell's common stock, and 20,521 shares of the series B preferred stock to Dr. Steven Victor, the principal shareholder of Intellicell, in exchange for an aggregate of 10,575,482 shares of IntelliCell's common stock, in exchange for 100% of the issued and outstanding shares of Intellicell common stock. The consideration issued in the Merger was determined as a result of arm's-length negotiations between the parties.

In addition to the foregoing, in accordance with the Merger Agreement, all outstanding IntelliCell Notes and IntelliCell Warrants shall entitle the holder to convert or exercise, as the case may be, into and receive the same number of shares of Company common stock as the holder of such Intellicell Notes and Intellicell Warrants would have been entitled to receive pursuant to the Merger had such holder exercised such Intellicell Notes and Intellicell Warrants in full immediately prior to the closing of the Merger. Thus, there are an aggregate of $1,385,000 of Intellicell Notes outstanding which are convertible into an aggregate of 1,573,864 shares of common stock of the Company (at a conversion price of $0.88) and warrants to purchase an aggregate of 3,076,189 shares of common stock of the Company (at an exercise price of $0.88).

The shares of our common stock and series B preferred stock issued to former holders of Intellicell's common stock in connection with the Merger were not registered under the Securities Act in reliance upon the exemption from registration provided by Section 4(2) of that Act and Regulation D promulgated under that section, which exempts transactions by an issuer not involving any public offering. These securities may not be offered or sold in the United States absent registration or an applicable exemption from the registration requirements. Certificates representing these securities contain a legend stating the same.

In connection with the Merger, the Company's former controlling shareholder entered into a return to treasury agreement pursuant to which he agreed to return to the Company for cancellation all of shares of series A preferred stock of the Company that had previously been issued to him (150,000 shares). The Company then cancelled those shares at the closing of the Merger.

Following the Merger, the Company will be changing its name to IntelliCell Biosciences, Inc., and our trading symbol is expected to be changed as well. As a result of the Merger, IntelliCell became our wholly-owned subsidiary, with Intellicell's former shareholders acquiring a majority of the outstanding shares of our common stock, as well as all of the shares of our series B preferred stock.

Description of Business of IntelliCell

Overview

Regenerative Medicine is a rapidly expanding set of innovative medical technologies that restore function by enabling the body to repair, replace, and regenerate damaged, aging or diseased cells, tissues and organs.

IntelliCell uses a proprietary system developed by its founder, Dr. Steven Victor, that provides it with the ability to extract, separate and process the stromal vascular fraction (SVF) containing stem cells from adipose (fat) tissue in about one hour. This system includes an ultrasonic cavitation (for which a provisional patent filed has been filed by the Company's founder, Dr. Steven Victor) and a flow cytometer that will allow for immediate verification of the quantity and viability of processed stem cells prior to the possible reintroduction back to the patient.

Intellicell believes that the adipose stromal vascular fraction derived from the application of its proprietary system yields a functionally diverse population of cells that are synergistic and able to communicate with other cells in their local environment. IntelliCell further believes that the mechanism of action of the stromal vascular fraction, which it has branded "IntelliCells™" is more than regenerative. The mixture of cells have multiple functions and are highly integrated and IntelliCell believes more potent then the adipose stem cells themselves.

IntelliCell further believes that the IntelliCells™, when returned to a patient's own body (autologous treatment), by way of same-day clinical procedure, have little or no risk of disease transfer, rejection or allergic reaction. IntelliCell also believe that IntelliCells™ have the potential to treat not only aesthetic conditions, but also a wide variety of clinical conditions involving orthopedic, gastrointestinal, periodontal, and autistic disorders.

Strategy

IntelliCell intends to initially focus on setting up tissue processing centers throughout the United States with managing partners. The centers will receive and employ the IntelliCell™ process to the adipose stromal vascular fraction harvested by physicians in their own offices, and then return the IntelliCells™ to the physicians the same day labeled "autologous homologous." The clinical use of these cells is not specified in labeling or promotion, but is left to the physicians in the exercise of their medical judgment. IntelliCell's second phase of its business is to establish "Centers of Excellence," which are intended to be upscale centers for administration of these therapies. These centers are anticipated to be set up in conjunction with physicians under an arrangement whereby the physician owns the professional corporation and IntelliCell is the exclusive managing agent for the professional corporation and pays all bills including salaries of physicians. After all expenses are paid, IntelliCell is paid the profit as a management fee. This arrangement is call a Friendly PC Model.. By doing this, the Company goal is to have multiple sources of revenue/business lines ---processing and management. Finally, IntelliCell is plans to collaborate with international partners to achieve optimal market entry opportunities and revenues.

IntelliCell has already established processing centers in New York City, Philadelphia, Dallas/Ft. Worth, and New Orleans, and has entered into a licensing agreement for a center in Palm Beach. In the future, the Company intends pursue expansion to secondary markets and beyond the U.S. through a combination of Company owned and licensed clinical facilities.

Research and Development

IntelliCell has had preliminary discussions with several researchers and Universities regarding the establishment of clinical studies at major medical centers throughout the United States for the purpose of exploring therapeutic use of IntelliCells. In the world literature IntelliCells have been used for aesthetic therapies (involving intradermal injections

of “IntelliCells™” for the treatment of wrinkles, skin tightening, acne scars, burns, scars), as well as in orthopedic (involving intradermal injections of “IntelliCells™” for the treatment of arthritis in knees, elbows and hands, as well as knee injections for cartilage repair) and rejuvenation therapies (involving intradermal injections of “IntelliCells™” for the treatment of hair growth and gum recession, and IV drip for general rejuvenation and osteoarthritis).

Competition

IntelliCell will compete with many pharmaceutical, biotechnology, medical device and bio tools companies, as well as other private and public stem cell companies involved in the development and commercialization of cell-based medical technologies and therapies. Regenerative medicine is a rapidly evolving industry, primarily through the development of cell-based therapies or devices designed to isolate cells from human tissues. Most efforts involve cell sources, such as bone marrow, embryonic and fetal tissue, umbilical cord and peripheral blood and skeletal muscle. Companies working in the area of regenerative medicine include, among others, Cytori Therapeutics, Stem Cell Assurance, Inc., Osiris, Aastrom Biosciences, Aldagen, BioTime, Baxter International, Celgene, Geron, Harvest Technologies, Mesoblast, Regenexx, NeoStem, X-Cell Center, Stem Cells, Athersys, and Tissue Genesis. Companies working in the area of biological tools include, among others, Life Technologies, Asterand, Pacific Biosciences of California, and AllCells. Many of IntelliCell's competitors and potential competitors have substantially greater financial, technological, research and development, marketing and personnel resources than we do. IntelliCell cannot with any accuracy forecast when or if these companies are likely to bring cell therapies to market for procedures that IntelliCell is also pursuing.

Employees

IntelliCell currently employs 3 persons, and it is currently working with approximately 200 independent sales representatives who recruit physicians interested in pursuing stem cell related therapies and utilizing the services offered by the Company's processing centers.

Intellectual Property

Intellicell's's founder Dr. Steven Victor has agreed to assign to IntelliCell, all of his right, title and interest in and to two provisional patents filed by him that IntelliCell intends to utilize in furtherance of its business. The application numbers and titles for these patents are:

61/427,221; UltraSonic Cavitation of Adipose Tissue to produce stromal vascular fraction; and

61/384,183; Stromal Vascular Fraction (SVF) or adipose derived regenerative cells (ADRC) used for intradermal injections for wrinkles, skin tightening, hair growth and mucous gum regeneration

Government Regulation

The health care industry is highly regulated in the United States. The federal government, through various departments and agencies, and state and local governments regulate and monitor the health care industry. The following is a general overview of the laws and regulations pertaining to our business.

Human cells, tissues, and cellular and tissue-based products ("HCT/Ps") Regulation

The U.S. Food and Drug Administration (the "FDA") regulates the manufacture of human cells, tissues, and cellular and tissue-based products ("HCT/Ps") under the authority of Section 361 of the Public Health Safety Act ("PHS Act") and exercises this authority pursuant to the regulations governing HCT/Ps in Part 1271 in Title 21 of the Code of Federal Regulations.

The FDA regulatory requirements for HCT/Ps, such as IntelliCells, are complex and evolving. The FDA sets forth criteria for determining whether an HCT/P can be regulated solely under Section 361 of the PHS Act, i.e. , as a "361 HCT/P." A 361 HCT/P is regulated solely as an HCT/P, without additional regulation as a medical device, drug, or biologic.

Under the FDA regulations, an HCT/P qualifies as a 361 HCT/P if it meets all of the following criteria: (i) it is minimally manipulated; (ii) it is intended for homologous use only, as reflected by labeling, advertising, or other indications of the manufacturer's objective intent; (iii) it is not combined with a device, drug or biologic (with limited exceptions); and (iv) either (a) it does not have a systemic effect and is not dependent upon metabolic activity for its primary function (with certain exceptions) or (b) it does have a systemic effect or is dependent upon metabolic activity for its primary function and is intended for certain uses, including autologous use. Such 361 HCT/Ps may be commercially distributed without the FDA's premarket clearance or approval. The FDA permits manufacturers to proceed to market based upon a self-determination that a product qualifies as a 361 HCT/P. The FDA reserves the right to disagree, and also has voluntary procedures for obtaining an advance agency determination. We believe the autologous stem cells that are derived from the IntelliCells process meet the FDA's requirements to be regulated solely as 361 HCT/Ps, and have proceeded to market on that basis.

The regulatory requirements of 21 C.F.R. Part 1271 applicable to HCT/Ps include the following:

- registration and listing of HCT/Ps with the FDA;
- current good tissue practices, specifically including requirements for the facilities, environmental controls, equipment, supplies and reagents, recovery of HCT/Ps from the patient, processing, storage, labeling and document controls, and distribution and shipment of the HCT/Ps to the laboratory, storage, or other facility;
- tracking and traceability of HCT/Ps and equipment, supplies, and reagents used in the manufacture of HCT/Ps;
- adverse event reporting;
- FDA inspection;
- importation of HCT/Ps; and
- abiding by any FDA order of retention, recall, destruction, and cessation of manufacturing of HCT/Ps.

Intellicell believes the donor screening requirements in Part 1271 do not apply because our product is made from autologous tissue.

Possible Additional FDA Device, Drug, or Biologic Regulatory Requirements

If the FDA were to disagree with our conclusion that IntelliCells qualify as a 361 HCT/P, then IntelliCells could be subject to additional FDA regulatory requirements applicable to medical devices or drugs under the Federal Food, Drug, and Cosmetic Act ("FDC Act") or biological products under Section 351 of the PHS Act and implementing regulations, depending upon which of these categories FDA concluded applies to IntelliCells.

Medical Device Regulation

The FDA regulates the design/development process, clinical testing, manufacture, safety, labeling, sale, distribution, and promotion of medical devices under the FDC Act. Included among these regulations are premarket clearance and premarket approval requirements, and the Quality System Regulation (which imposes Good Manufacturing Practice requirements). Other statutory and regulatory requirements govern, among other things, registration and inspection, medical device listing, prohibitions against misbranding and adulteration, labeling, and post-market reporting.

The regulatory clearance/approval process can be lengthy, expensive, and uncertain. Unless an exemption applies, any medical device that we would bring to market must first receive either premarket notification clearance (by making a 510(k) submission) or premarket approval (by filing a premarket approval application ("PMA")) from the FDA pursuant to the FDC Act. In addition, certain modifications made to marketed devices also may require 510(k) clearance or approval of a PMA supplement. The FDA's 510(k) clearance process usually takes from four to twelve months, but it may take longer. The process of obtaining PMA approval is much more costly and uncertain and may take one or more years from the time the process is initiated. IntelliCell cannot be sure that 510(k) clearance or PMA approval will be obtained for any product that we propose to market.

A clinical study in support of a PMA application or 510(k) submission for a "significant risk" device requires an Investigational Device Exemption ("IDE") application approved in advance by the FDA for a limited number of patients. The IDE application must be supported by appropriate data, such as animal and laboratory testing results. If the device presents a "non-significant risk" to the patient, a sponsor may begin the clinical study without the need for FDA approval. In all cases, the clinical study must be conducted under the auspices of an Institutional Review Board ("IRB") pursuant to the FDA's regulatory requirements intended for the protection of subjects and to assure the integrity and validity of the data.

Medical devices are subject to post-market reporting requirements when the device may have caused or contributed to the death or serious injury, and for certain device malfunctions that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. If safety or effectiveness problems occur after the product reaches the market, the FDA may take steps to prevent or limit further marketing of the product. The FDA actively enforces regulations prohibiting marketing and promotion of devices for indications or uses that have not been cleared or approved by the FDA. Modifications or enhancements of products that could affect the safety or effectiveness or effect a major change in the intended use of a device that was either cleared through the 510(k) process or approved through the PMA process may require further FDA review through new 510(k) or PMA submissions.

Failure to comply with applicable requirements can result in application integrity proceedings, fines, recalls or seizures of products, injunctions, civil penalties, total or partial suspensions of production, withdrawals of existing product approvals or clearances, refusals to approve or clear new applications or notifications, and criminal prosecution.

Drug and Biological Product Regulation

To obtain approval of a drug or biological product from the FDA, a company must, among other requirements, submit data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product. In most cases, this entails extensive laboratory tests and preclinical and clinical trials. The collection of these data, as well as the preparation of applications for review by the FDA, are costly in time and effort, and may require significant capital investment.

A company typically conducts human clinical trials in three sequential phases, but the phases may overlap. Phase 1 trials consist of testing of the product in a small number of patients or healthy volunteers, primarily for safety at one or more doses. Phase 2 trials, in addition to safety, evaluate the efficacy of the product in a patient population somewhat larger than Phase 1 trials. Phase 3 trials typically involve additional testing for safety and clinical efficacy in an expanded population at geographically dispersed test sites. A company must submit to the FDA a protocol, which must also be approved by the IRBs at the institutions participating in the trials, prior to commencement of each clinical trial. The trials must be conducted in accordance with the FDA's good clinical practices. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time.

To obtain marketing authorization, a company must submit to the FDA the results of the preclinical and clinical testing, together with, and among other things, detailed information on the manufacture and composition of the product, in the form of a new drug application ("NDA"), or, in the case of a biologic, a biologics license application ("BLA"). Under federal law, the submission of most NDAs and BLAs is subject to a substantial application user fee, currently exceeding $1.5 million, and the manufacturer and/or sponsor under an approved NDA or BLA are also subject to annual product and establishment user fees, currently exceeding $86,000 per product and $497,000 per establishment. These fees are typically increased annually. We cannot be sure that NDA or BLA approval would be obtained for any product that we propose to market.

All approved drug and biological products are subject to continuing regulation by the FDA, including record-keeping requirements, reporting of adverse experiences with the product, sampling and distribution requirements, notifying the FDA and gaining its approval of certain manufacturing or labeling changes, complying with certain electronic records and signature requirements, submitting periodic reports to the FDA, maintaining and providing updated safety and efficacy information to the FDA, and complying with FDA promotion and advertising requirements. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, seizure of product, injunctive action, criminal prosecution, or civil penalties.

The FDA may require post-marketing studies or clinical trials to develop additional information regarding the safety of a product. These studies or trials may involve continued testing of a product and development of data, including clinical data, about the product's effects in various populations and any side effects associated with long-term use. The FDA may require post-marketing studies or trials to investigate known serious risks or signals of serious risks or identify unexpected serious risks and may require periodic status reports if new safety information develops. Failure to conduct these studies in a timely manner may result in substantial civil fines.

Drug and biological product manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and to list their products with the FDA. The FDA periodically inspects manufacturing facilities in the United States and abroad in order to assure compliance with the applicable current good manufacturing practices ("cGMP") regulations and other requirements. Facilities also are subject to inspections by other federal, foreign, state, or local agencies. In complying with the cGMP regulations, manufacturers must continue to expend time, money and effort in record-keeping and quality control to assure that the product meets applicable specifications and other post-marketing requirements. We must ensure that any third-party manufacturers continue to expend time, money and effort in the areas of production, quality control, record keeping and reporting to ensure full compliance with those requirements. Failure to comply with these requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing or recall or seizure of product.

Newly discovered or developed safety or efficacy data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, additional preclinical or clinical studies, or even in some instances, revocation or withdrawal of the approval. Violations of regulatory requirements at any stage, including after approval, may result in various adverse consequences, including the FDA's withdrawal of an approved product from the market, other voluntary or FDA-initiated action that could delay or restrict further marketing, and the imposition of civil fines and criminal penalties against the manufacturer and NDA or BLA holder. Later discovery of previously unknown problems may result in restrictions on the product, manufacturer or NDA or BLA holder, including withdrawal of the product from the market. New government requirements may be established that could delay or prevent regulatory approval, or affect the conditions under which approved products are marketed.

State and Local Government Regulation

Some states and local governments regulate human tissue banking facilities and require these facilities to obtain specific licenses. IntelliCell's processing centers may be required to comply with such state laws, including becoming licensed as a tissue bank and being subject to inspection. Some states, such as New York, California and Maryland, may require licensure of out-of-state facilities that process tissue of residents of those states. Intellicell must obtain the applicable state licensures for it's processing centers and comply with the current and any new licensing laws that become applicable in the future.

Health Insurance Portability and Accountability Act—Protection of Patient Health Information

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") included the Administrative Simplification provisions that require the Secretary of the Department of Health and Human Services ("HHS") to publicize standards for the electronic exchange, privacy, and security of health information. HHS published the Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule") and the Security Standards for the Protection of Electronic Protected Health Information ("Security Rule") to protect the privacy and security of certain health information. The Privacy Rule addresses the use and disclosure of an individual's protected health information by covered entities and applies to health plans, health care clearinghouses, and any health care provider who transmits health information in electronic format. In addition to these entities, the Privacy Rule also applies to business associates and requires certain requirements to be placed in contracts between business associates and covered entities.

The Security Rule establishes a national security standard for protecting certain health information that is held or transferred in electronic form. The Security Rule implements the protections in the Privacy Rule by addressing the technical and non-technical safeguards that covered entities must put in place to secure individuals' electronic protected health information.

Companies failing to comply with the HIPAA standards may be subject to civil money penalties or criminal prosecution. To the extent that IntelliCell's business requires compliance with HIPAA, it intends to fully comply with all requirements.

Other Applicable U.S. Laws

In addition to the above-described regulation by United States federal and state government, the following are other federal and state laws and regulations that could directly or indirectly affect our ability to operate the business:

- state and local licensure, registration, and regulation of the development of pharmaceuticals and biologics;