ADVANCED CELL TECHNOLOGY, INC.
Form 8-K
September 26, 2007

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): **September 20, 2007**

ADVANCED CELL TECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware	**000-50295**	**87-0656515**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

1201 Harbor Bay Parkway, Alameda, California 94502
(Address of principal executive offices, including zip code)

(510) 748-4900
(Registrant s telephone number, including area code)

(Former name or former address, if changed since last report)

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 CAR 240.13e-4(c))

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

ITEM 1.01 Entry into a Material Definitive Agreement.

Amended and Restated Consulting Agreement with Nabil Dib, M.D.

On September 20, 2007, Advanced Cell Technology, Inc., a Delaware corporation (the Company), entered into that certain Amended and Restated Consulting Agreement with Nabil Dib, M.D., in connection with the completion of the acquisition of Mytogen, Inc. as further described under Item 2.01 below. The consulting agreement with Dr. Dib provides that Dr. Dib will perform certain consulting services to the Company in the connection with the myoblast transplantation program and hemangioblast program. Pursuant to the Consulting Agreement, Dr. Dib shall receive monthly compensation of up to $50,000 depending on the specific services provided. The consulting agreement requires the completion of Statements of Work for each consulting project and provides for termination by the Company with or without cause under certain defined circumstances.

Employment Agreement with Jonathan Dinsmore, Ph.D.

On September 20, 2007, we entered into an Employment Agreement with Jonathan Dinsmore, Ph.D., who will serve as the Company s Vice President & General Manager Mytogen. Dr. Dinsmore was most recently President and Chief Scientific Officer and served as a director of Mytogen, Inc. Prior to his current position with Mytogen, he directed both clinical and preclinical research programs at both Diacrin, Inc. (Nasdaq: DCRN) and GenVec, Inc. (Nasdaq: DCRN). He has research and clinical experience in the development of therapeutic products to treat Parkinson s disease, Huntington s disease, epilepsy, stroke, spinal cord injury, chronic intractable pain, liver disease, and cardiovascular disease. Dr. Dinsmore received a B.S. in Biology from Boston College in 1983 and his Ph.D. in Biology from Dartmouth College in 1988. He then trained four years as a Post-doctoral Fellow at Massachusetts Institute of Technology, after which he joined Diacrin in 1992. His extensive accomplishments include numerous awarded and pending patents as well as diverse published studies on myoblast transplantation technology.

The employment agreement with Dr. Dinsmore provides for annual compensation of $235,000. The agreement provides for an annual bonus as determined by our Chief Executive Officer and our Board of Directors. Dr. Dinsmore was awarded 400,000 stock options to be issued under the 2005 Stock Incentive Plan, vesting in equal monthly installments over 48 months. In the event of a change of control of us, 50% of any unvested options held by Dr. Dinsmore will become vested. In the event Dr. Dinsmore s employment is terminated without cause by us or for good reason by Dr. Dinsmore, he is entitled to a lump sum severance payment equal to three months base salary, accelerated vesting of 25% of his unvested stock options, and reimbursed cost of medical coverage for a period of twelve months. In the event Dr. Dinsmore is terminated without cause following a change of control, he is entitled to a lump sum severance payment equal to three months base salary and accelerated vesting of 25% of any unvested stock options. Dr. Dinmore s agreement contains non-solicitation, confidentiality and non-competition covenants. The agreement may be terminated by either party with or without cause with thirty days written notice.

ITEM 2.01 Completion of Acquisition or Disposition of Assets.

Acquisition of Mytogen, Inc.

On September 20, 2007, the Company completed the acquisition of Mytogen, Inc., a Delaware corporation, pursuant to the terms of the previously announced Agreement and Plan of Merger dated July 31, 2007. In connection with the closing, ACT Acquisition Sub, Inc., a Delaware corporation and a wholly owned subsidiary of the Company (Merger Sub), will merge with and into Mytogen, with Mytogen continuing as the surviving entity and a wholly owned subsidiary of the Company (the Merger).

Certain equity holders of Mytogen receive (i) shares of common stock of the Company having an aggregate value of $5,000,000 based on a per share price of $0.62 (the Consideration Shares), and/or (ii) warrants to purchase an aggregate of 1,500,000 shares of common stock of the Company at an exercise price of $0.75 per share. Fifteen percent (15%) of the Consideration Shares were deposited into escrow at the closing in order to secure certain indemnification obligations of Mytogen.

The acquisition of Mytogen results in the expansion of the Company s research and development programs

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and product candidates. Specifically, the Company will expand beyond its human embryonic stem cell research and development into specific product candidates involving autologous myoblast transplantation therapy. Our mytoblast program is developing an autologous myoblast transplantation therapy delivered using a minimally invasive catheter injection system to restore cardiac function in patients with advanced heart disease. The key target for the therapy will be heart failure patients with New York Heart Association (NYHA) scores Class II to IV. The Company s therapy could also benefit patients supported on ventricular assistance devices and potential additional indications, such as acute myocardial infarction, peripheral artery disease, and non-cardiac tissue repair. Currently available treatment options for heart failure patients are inadequate and can only slow the progression of heart failure; none can halt or reverse the process. We believe our autologous myoblast transplantation therapy uses patented myoblast compositions for catheter delivery to the heart offering repair of the disease in heart failure patients and for those end-stage disease patients on ventricular assistance device support. These indications represent a significant unmet medical need and hold significant potential for clinical approval.

Our transplantation therapy involves extraction through simple biopsy from a patient s thigh of myoblasts, which are non-embryonic, skeletal muscle stem cells, that can be expanded in culture and injected back into damaged and scarred regions of the heart. This therapy promotes repair of damaged cardiac tissue by autologous cells, thereby avoiding immune rejection as each patient receives their own cells. Skeletal muscle, unlike heart muscle, can repair itself after injury. Skeletal muscle contains immature myoblasts that can fuse with surrounding myoblasts or with damaged muscle fibers to regenerate contractile skeletal muscle. In experimental models, our researchers have demonstrated that skeletal myoblasts can be transplanted into an infarcted myocardium with the subsequent development of elongated, striated cells characteristic of both skeletal and cardiac muscle. Our Phase I clinical studies have demonstrated the efficacy of this therapy on a preliminary basis. Our Phase II and III studies planned for commencement in 2008 will evaluate the applications for myoblast transplantation in slowing and/or reversing the impact of heart failure.

We perform our myoblast expansion, packaging, shipment, and quality testing using proprietary procedures that adhere to GMP regulations for manufacturing clinical trial material. This process is housed at our Charleston, Massachusetts facility, acquired in the Mytogen transaction. After expansion, the myoblasts are packaged and delivered to the clinical site for implantation into the injured heart tissue by a surgeon or interventional cardiologist. To maximize cell therapy effectiveness, adequate numbers of cells must be delivered to the site of damage in a repeatable and safe manner. Our therapy utilizes a minimally invasive catheter-based delivery methodology, which provides a safe, targeted and high efficiency approach to cell delivery to the infarct area.

We believe that, unlike currently available treatment options, myoblast therapy has the ability to repair and improve the function of a damaged heart. Our preclinical and clinical studies support the conclusion that our therapy presents significant advantages over currently available treatments, including:

- Ability to restore cardiac function through new muscle formation
- Ability to prevent further decline of heart function
- No risk immunological rejection of myoblasts due to autologous nature of the therapy
- Complementary to and capable of improving outcomes of current therapeutic options for heart disease

We believe our myoblast technology has demonstrated that a myoblast transplantation treatment is feasible and safe in clinical trials conducted to date and that the technology could address the large market potential presented by congestive heart failure, myocardial infarction and other cardiovascular diseases. Our myoblast program is at a more advanced stage of development than our human embryonic stem cell based technologies. Our myoblast program has received FDA clearance to proceed to Phase II human clinical trials. We have completed preclinical testing, two multi-center Phase I clinical trails and a multi-center Phase Ib clinical trial of our myoblast cell transplantation product and we anticipate initiating at least one multi-regional, pivotal Phase II/III study in 2008. By contrast, our human embryonic stem cell-based technologies are not yet in clinical trials, but we believe these technologies have potentially broader and more powerful applications with respect to a wide range of diseases.

The Mytogen acquisition includes an intellectual property portfolio supporting our myoblast program. The following table identifies the issued patents that we own or license that we believe currently support this technology.

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

Number Patent	Country	Filing Date	Issue Date	Expiration Date	Title
6,673,604	United States (US)	07/24/00	1/06/04		Muscle Cells and Their Use in Cardiac Repair*
6,432,711	United States (US)		8/13/02		Embryonic Stem Cells Capable of Differentiating into Desired Cell Lines
5,543,316	United States (US)	04/20/94	08/06/96		Injectable Culture Medium for Maintaining Viability of Myoblast Cells
770889	Australia (AU)	7/24/00	06/17/04		Muscle Cells and Their Use in Cardiac Repair
2,174,746	Canada (CA)		04/24/07		Embryonic Stem Cells Capable of Differentiating into Desired Cell Lines

* Currently undergoing inter partes reexamination

Also included in the intellectual property acquired in the Mytogen transaction are the following key licenses:

Cardion License. Cardion Pharmaceuticals, Inc. and Diacrin, Inc. entered into a patent license agreement on September 30, 2002. The agreement was transferred to our wholly owned subsidiary Mytogen, Inc. on December 28, 2005. Under the agreement, Mytogen has a worldwide, non-exclusive right and license under certain specified patent rights, with the right to sublicense, to make, have made, use, have used, offer for sale, sell, lease, import and/or otherwise dispose of products in the field described as cell-transplantation treatments and related therapies that use genetically unmodified skeletal myoblasts for the treatment of cardiovascular disease. Under the agreement Mytogen is required to make certain milestone payments (ranging from $500,000 to $1,500,000 upon the occurrence of specified events), an annual maintenance fee of $25,000.00, and earned royalties equal to (i) 5% of the net sales price of all covered products sold to its end-user customers and (ii) 5% of net sales of covered products sold by Mytogen s sublicensees.

GenVec Agreement. On December 28, 2005, Mytogen and GenVec, Inc. entered into a patent assignment and security agreement. Under the agreement, as amended on July 31, 2007, GenVec assigned certain agreements and intellectual property to Mytogen, and retained a royalty-free non-exclusive license, with the right to grant sublicenses, to practice the intellectual property in connection with products, processes or services developed or provided by GenVec other than autologous and allogenic skeletal myoblasts for cardiac therapy. Under the original agreement, Mytogen granted a security interest in the assigned intellectual property, but the security interest was released in the amendment to the agreement. Under the agreement, as amended, Mytogen must use commercially reasonable efforts to commercialize the assigned intellectual property, including by spending specified amounts in support of research and development in support of such commercialization; Mytogen must pay GenVec one-half of the first milestone payment (anticipated to be two million U.S. dollars) received by Mytogen under the Terumo Agreement; and Mytogen must also pay GenVec four percent (4%) of the net sales revenue from sales or other provision of products, processes or services covered by the agreement.

Terumo License. Our Mytogen subsidiary licenses certain of its technology to Terumo Corporation. Diacrin, Inc. and Terumo Corporation entered into a development and license agreement on September 4, 2002; the agreement was transferred to Mytogen, Inc. on December 28, 2005. Under the agreement, the parties agreed to collaborate to develop and commercialize products in the field described as autologous skeletal myoblasts for cardiac therapy (and conditionally allogenic skeletal myoblasts for cardiac therapy) in Japan and such other Asian countries as the parties may agree. Pursuant to the agreement Terumo has an exclusive, royalty-bearing license, with a limited right to grant sublicenses, under certain technology and patent rights controlled by Mytogen; and a non-exclusive, non-royalty bearing right and license to use certain data resulting from clinical trials for products based on the licensed technology and patent rights for purposes of seeking regulatory approvals. The agreement specifies the rights and obligations of the parties with respect to collaboration and development of products covered by the agreement. The agreement also

requires Terumo to make certain milestone payments, including the following: $2 million upon initiation of any clinical trials of any covered product in Japan; $2 million upon the first filing for regulatory approval of a covered product in Japan; $1 million upon the first filing for regulatory approval of a covered product in any country other than Japan if the territory is expanded to include countries other than Japan; $2 million upon the first commercial sale of a covered product in Japan; and $1 million upon the first commercial sale of a covered product in any country other than Japan if the territory is expanded to include countries other than Japan. Terumo is also required under the agreement to pay royalties in an amount equal to ten percent (10%) of the net sales on covered products.

Liquidity and Capital Resources

As disclosed in our Current Report on Form 8-K with the Securities and Exchange Commission on August 31, 2007, we recently closed on the issuance of $12,250,000 of our amortizing senior secured convertible debentures and associated warrants (2007 Financing). The net proceeds of this transaction equaled $10 million less placement agent fees. The net proceeds of this financing will be used, in part, to fund our Myoblast research, development and clinical programs.

Additional Risk Factors

The introduction of the myoblast product candidate and associated clinical testing into the Company s operations, together with the issuance of secured debentures in connection with the 2007 Financing, makes certain additional risks relevant to consideration of an investment in our common stock. The risks described below are in addition to the risk factors appearing in the Company s current flings with the Securities and Exchange Commission.

Risks Related to Product Development

Limited experience in conducting and managing preclinical development activities, clinical trials and the application process necessary to obtain regulatory approvals. Our limited experience in conducting and managing preclinical development activities, clinical trials and the application process necessary to obtain regulatory approvals might prevent us from successfully designing or implementing a preclinical study or clinical trial. If we do not succeed in conducting and managing our preclinical development activities or clinical trials, or in obtaining regulatory approvals, we might not be able to commercialize our product candidates, or might be significantly delayed in doing so, which will materially harm our business.

None of the products that we are currently developing has been approved by the FDA or any similar regulatory authority in any foreign country. Our ability to generate revenues from any of our product candidates will depend on a number of factors, including our ability to successfully complete clinical trials, obtain necessary regulatory approvals and implement our commercialization strategy. In addition, even if we are successful in obtaining necessary regulatory approvals and bringing one or more product candidates to market, we will be subject to the risk that the marketplace will not accept those products. We may, and anticipate that we will need to, transition from a company with a research and development focus to a company capable of supporting commercial activities and we may not succeed in such a transition.

Because of the numerous risks and uncertainties associated with our product development and commercialization efforts, we are unable to predict the extent of our future losses or when or if we will become profitable. Our failure to successfully commercialize our product candidates or to become and remain profitable could depress the market price of our common stock and impair our ability to raise capital, expand our business, diversify our product offerings and continue our operations.

Our approach of using cell-based therapy for the treatment of heart damage is risky and unproven and no products using this approach have received regulatory approval in the United States or Europe. We believe that no company has yet been successful in its efforts to obtain regulatory approval in the United States or Europe of a cell-based therapy product for the treatment of heart disease in humans. Cell-based therapy products, in general, may be susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy or other characteristics that may prevent or limit their approval by regulators or commercial use. Many companies in the industry have suffered significant setbacks in advanced clinical trials, despite promising results in earlier trials.

If our clinical trials are unsuccessful or significantly delayed, or if we do not complete our clinical trials, we will not receive regulatory approval for or be able to commercialize our product candidates. Our lead product candidate, our myoblast program, is still in clinical testing and has not yet received approval from the FDA or any similar foreign regulatory authority for any indication. Although this product candidate has received positive results in Phase I and Ib clinical trials, it may never receive regulatory approval or be commercialized in the United States or other countries.

We cannot market any product candidate until regulatory agencies grant approval or licensure. In order to obtain regulatory approval for the sale of any product candidate, we must, among other requirements, provide the FDA and similar foreign regulatory authorities with preclinical and

clinical data that demonstrate to the satisfaction of regulatory authorities that our product candidates are safe and effective for each indication under the applicable standards relating to such product candidate. The preclinical studies and clinical trials of any product candidates must comply with the regulations of the FDA and other governmental authorities in the United States and similar agencies in other countries.

Even though we have achieved positive interim results in clinical trials, these results do not necessarily predict final results, and positive results in early trials may not be indicative of success in later trials. For example, our myoblast program has been studied in a limited number of patients to date. Even though our early data has been promising, we have not yet completed any large-scale pivotal trials to establish the safety and efficacy of this therapy. There is a risk that safety concerns relating to our product candidates or cell-based therapies in general will result in the suspension or termination of our clinical trials.

We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent regulatory approval and/or commercialization of our product candidates, including the following:

- the FDA or similar foreign regulatory authorities may find that our product candidates are not sufficiently safe or effective or may find our cell culturing processes or facilities unsatisfactory;

- officials at the FDA or similar foreign regulatory authorities may interpret data from preclinical studies and clinical trials differently than we do;

- our clinical trials may produce negative or inconclusive results or may not meet the level of statistical significance required by the FDA or other regulatory authorities, and we may decide, or regulators may require us, to conduct additional preclinical studies and/or clinical trials or to abandon one or more of our development programs;

- the FDA or similar foreign regulatory authorities may change their approval policies or adopt new regulations;

- there may be delays or failure in obtaining approval of our clinical trial protocols from the FDA or other regulatory authorities or obtaining institutional review board approvals or government approvals to conduct clinical trials at prospective sites;

- we, or regulators, may suspend or terminate our clinical trials because the participating patients are being exposed to unacceptable health risks or undesirable side effects;

- we may experience difficulties in managing multiple clinical sites;

- enrollment in our clinical trials for our product candidates may occur more slowly than we anticipate, or we may experience high drop-out rates of subjects in our clinical trials, resulting in significant delays;

- we may be unable to manufacture or obtain from third party manufacturers sufficient quantities of our product candidates for use in clinical trials; and

- our product candidates may be deemed unsafe or ineffective, or may be perceived as being unsafe or ineffective, by healthcare providers for a particular indication.

We depend on third parties to assist us in the conduct of our preclinical studies and clinical trials, and any failure of those parties to fulfill their obligations could result in costs and delays and prevent us from obtaining regulatory approval or successfully commercializing our product candidates on a timely basis, if at all. We engage consultants and contract research organizations to help design, and to assist us in conducting, our preclinical studies and clinical trials and to collect and analyze data from those studies and trials. The consultants and contract research organizations we engage interact with clinical investigators to enroll patients in our clinical trials. As a result, we depend on these consultants and contract research organizations to perform the studies and trials in accordance with the investigational plan and protocol for each product candidate and in compliance with regulations and standards, commonly referred to as good clinical practice , for conducting, recording and reporting results of clinical trials to assure that the data and results are credible and accurate and the trial participants are adequately protected, as required by the FDA and foreign regulatory agencies. We may face delays in our regulatory approval process if these parties do not perform their obligations in a timely or

competent fashion or if we are forced to change service providers.

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

We must comply with extensive government regulations in order to obtain and maintain marketing approval for our products in the United States and abroad. If we do not obtain regulatory approval for our product candidates, we may be forced to cease our operations. Our product candidates are subject to extensive regulation in the United States and in every other country where they will be tested or used. These regulations are wide-ranging and govern, among other things:

- product design, development, manufacture and testing;
- product safety and efficacy;
- product labeling;
- product storage and shipping;
- record keeping;
- pre-market clearance or approval;
- advertising and promotion; and
- product sales and distribution.

We cannot market our product candidates until we receive regulatory approval. The process of obtaining regulatory approval is lengthy, expensive and uncertain. Any difficulties that we encounter in obtaining regulatory approval may have a substantial adverse impact on our business and cause our stock price to decline significantly.

In the United States, the FDA imposes substantial requirements on the introduction of biological products and many medical devices through lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Satisfaction of these requirements typically takes several years and the time required to do so may vary substantially based upon the type and complexity of the biological product or medical device.

In addition, product candidates that we believe should be classified as medical devices for purposes of the FDA regulatory pathway may be determined by the FDA to be biologic products subject to the satisfaction of significantly more stringent requirements for FDA approval.

The requirements governing the conduct of clinical trials and cell culturing and marketing of our product candidates outside the United States vary widely from country to country. Foreign approvals may take longer to obtain than FDA approvals and can require, among other things, additional testing and different clinical trial designs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval processes. Some foreign regulatory agencies also must approve prices of the products. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. We may not be able to file for regulatory approvals and may not receive necessary approvals to market our product candidates in any foreign country. If we fail to comply with these regulatory requirements or fail to obtain and maintain required approvals in any foreign country, we will not be able to sell our product candidates in that country and our ability to generate revenue will be adversely affected.

We cannot assure you that we will obtain FDA or foreign regulatory approval to market any of our product candidates for any indication in a timely manner or at all. If we fail to obtain regulatory approval of any of our

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

product candidates for at least one indication, we will not be permitted to market our product candidates and may be forced to cease our operations.

Even if some of our product candidates receive regulatory approval, these approvals may be subject to conditions, and we and our third party manufacturers will in any event be subject to significant ongoing regulatory obligations and oversight. Even if any of our product candidates receives regulatory approval, the manufacturing, marketing and sale of our product candidates will be subject to stringent and ongoing government regulation. Conditions of approval, such as limiting the category of patients who can use the product, may significantly impact our ability to commercialize the product and may make it difficult or impossible for us to market a product profitably. Changes we may desire to make to an approved product, such as cell culturing changes or revised labeling, may require further regulatory review and approval, which could prevent us from updating or otherwise changing an approved product. If our product candidates are approved by the FDA or other regulatory authorities for the treatment of any indications, regulatory labeling may specify that our product candidates be used in conjunction with other therapies.

Once obtained, regulatory approvals may be withdrawn for a number of reasons, including the later discovery of previously unknown problems with the product. Regulatory approval may also require costly post-marketing follow-up studies, and failure of our product candidates to demonstrate sufficient efficacy and safety in these studies may result in either withdrawal of marketing approval or severe limitations on permitted product usage. In addition, numerous additional regulatory requirements relating to, among other processes, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping will also apply. Furthermore, regulatory agencies subject a marketed product, its manufacturer and the manufacturer s facilities to continual review and periodic inspections. Compliance with these regulatory requirements are time consuming and require the expenditure of substantial resources.

If any of our product candidates is approved, we will be required to report certain adverse events involving our products to the FDA, to provide updated safety and efficacy information and to comply with requirements concerning the advertisement and promotional labeling of our products. As a result, even if we obtain necessary regulatory approvals to market our product candidates for any indication, any adverse results, circumstances or events that are subsequently discovered, could require that we cease marketing the product for that indication or expend money, time and effort to ensure full compliance, which could have a material adverse effect on our business.

Any failure by us, or by any third parties that may manufacture or market our products, to comply with the law, including statutes and regulations administered by the FDA or other U.S. or foreign regulatory authorities, could result in, among other things, warning letters, fines and other civil penalties, suspension of regulatory approvals and the resulting requirement that we suspend sales of our products, refusal to approve pending applications or supplements to approved applications, export or import restrictions, interruption of production, operating restrictions, closure of the facilities used by us or third parties to manufacture our product candidates, injunctions or criminal prosecution. Any of the foregoing actions could have a material adverse effect on our business.

The healthcare community has relatively little experience with therapies based on cellular medicine and, accordingly, if our product candidates do not become widely accepted by physicians, patients, third party payors or the healthcare community, we may be unable to generate significant revenue, if any.

We are developing cell-based therapy product candidates for the treatment of heart damage that represent novel and unproven treatments and, if approved, will compete with a number of more conventional products and therapies manufactured and marketed by others, including major pharmaceutical companies. We cannot predict or guarantee that physicians, patients, healthcare insurers, third party payors or health maintenance organizations, or the healthcare community in general, will accept or utilize any of our product candidates. We anticipate that, if approved, we will market our myoblast product primarily to interventional cardiologists, who are generally not the primary care physicians for patients who may be eligible for treatment with MyoCell. Accordingly, our commercial success may be dependent on third party physicians referring their patients to interventional cardiologists for MyoCell treatment.

If we are successful in obtaining regulatory approval for any of our product candidates, the degree of market acceptance of those products will depend on many factors, including:

- our ability to provide acceptable evidence and the perception of patients and the healthcare community, including third party payors, of the positive characteristics of our product candidates relative to existing treatment methods, including their safety, efficacy, cost effectiveness and/or other potential advantages;

- the incidence and severity of any adverse side effects of our product candidates;

- the availability of alternative treatments;

- the labeling requirements imposed by the FDA and foreign regulatory agencies, including the scope of approved indications and any safety warnings;

- our ability to obtain sufficient third party insurance coverage or reimbursement for our products candidates;

- the inclusion of our products on insurance company coverage policies;

- the willingness and ability of patients and the healthcare community to adopt new technologies;

- the procedure time associated with the use of our product candidates;

- our ability to manufacture or obtain from third party manufacturers sufficient quantities of our product candidates with acceptable quality and at an acceptable cost to meet demand; and

- marketing and distribution support for our products.

Failure to achieve market acceptance would limit our ability to generate revenue and would have a material adverse effect on our business. In addition, if any of our product candidates achieve market acceptance, we may not be able to maintain that market acceptance over time if competing products or technologies are introduced that are received more favorably or are more cost-effective.

Risks Relating to the September 2005, September 2006, and August 2007 Financings

If we are required for any reason to repay our outstanding debentures we would be required to deplete our working capital, if available, or raise additional funds. Our failure to repay the convertible debentures, if required, could result in legal action against us, which could require the sale of substantial assets. We have outstanding, as of September 1, 2007, $23,479,420 aggregate original principal amount of convertible debentures with an original issue discount of 20.3187% with $12,550,000 in 2007 Debentures, $8,259,767 in 2006 Debentures, and $2,669,653 in 2005 Debentures. We are required to redeem on a monthly basis, by payment, at our option, with cash or with shares of our common stock, 1/30th of the aggregate original principal amount of the debentures.

The 2005 Debentures are due and payable on September 14, 2008, unless sooner converted into shares of our common stock, the 2006 Debentures are due and payable on February 28, 2010, and the 2007 Debentures are due and payable on August 31, 2010, unless sooner converted into shares of our common stock. Any event of default could require the early repayment of the convertible debentures, including the accruing of interest on the outstanding principal balance of the debentures if the default is not cured with the specified grace period. We anticipate that the full amount of the convertible debentures will be converted into shares of our common stock, in accordance with the terms of the convertible debentures. If, prior to the maturity date, we are required to repay the convertible debentures in full, we would be required to use our limited working capital and raise additional funds. If we were unable to repay the notes when required, the debenture holders could commence legal action against us to recover the amounts due. Any such action could require us to curtail or cease operations.

There are a large number of shares underlying our convertible debentures in full, and warrants that are registered and available for sale and the sale of these shares may depress the market price of our common stock. As of September 1, 2007, we had:

- certain outstanding 2005 Debentures that may be converted into an estimated 7,851,920 shares of common stock based on a conversion price of $0.34, and

- outstanding 2005 Warrants to purchase 2,335,005 shares of common stock with an exercise price of $0.34 that were issued in connection with the sale of the 2005 Debentures, and

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- outstanding replacement warrants to purchase 12,689,966 shares of common stock with an exercise price of $0.34, and

- outstanding 2006 Debentures that may be converted into an estimated 28,679,747 shares of common stock based on a conversion price of $0.288, and

- outstanding 2006 warrants to purchase 23,640,191 shares of common stock with an exercise price of $0.3168 that were issued in connection with the sale of the 2006 Debentures, and

- certain outstanding 2007 Debentures that may be converted into an estimated 36,911,765 shares of common stock based on a conversion price of $0.34, and

- outstanding 2007 Warrants to purchase 43,240,655 shares of common stock with an exercise price of $0.34 that were issued in connection with the sale of the 2007 Debentures.

Sales of a substantial number of shares of our common stock in the public market could adversely affect the market price for our common stock and make it more difficult for you to sell shares of our common stock at times and prices that you feel are appropriate.

The issuance of shares upon conversion of the convertible debentures and exercise of outstanding warrants will cause immediate and substantial dilution to our existing stockholders. The issuance of shares upon conversion of the convertible debentures and exercise of warrants, including the replacement warrants, will result in substantial dilution to the interests of other stockholders since the selling security holders may ultimately convert and sell the full amount issuable on conversion. Although no single selling security holder may convert its convertible debentures and/or exercise its warrants if such conversion or exercise would cause it to own more than 4.99% of our outstanding common stock, this restriction does not prevent each selling security holder from converting and/or exercising some of its holdings and then converting the rest of its holdings. In this way, each selling security holder could sell more than this limit while never holding more than this limit. There is no upper limit on the number of shares that may be issued which will have the effect of further diluting the proportionate equity interest and voting power of holders of our common stock, including investors in this offering. In addition, the issuance of the 2007 Debentures and the 2007 Warrants triggered certain anti-dilution rights for certain third parties currently holding our securities resulting in substantial dilution to the interests of other stockholders.

Payment of mandatory monthly redemptions in shares of common stock will result in substantial dilution. We expect to satisfy all or a significant portion of our obligation to redeem 1/30th of the aggregate original principal amount of debentures per month through issuance of additional shares of our common stock. This approach will result in substantial dilution to the interests of other stockholders. In addition, several of our outstanding securities contain antidilution protections that will result in further dilution in the event the redemption prices associated with monthly redemptions are below $0.25 per share of our common stock.

If we fail to effect and maintain registration of the common stock issued or issuable pursuant to conversion of our debentures, or upon exercise of our warrants, we may be obligated to pay the investors of those securities liquidated damages. We have various obligations to file and obtain the effectiveness of certain registration statements which include certain outstanding common stock and common stock underlying outstanding debentures and common stock underlying the warrants. If we fail to meet any obligations we have to have effective and current registration statements available (including the current registration statement related to the common stock underlying our debentures and warrants), we may become obligated to pay liquidated damages to investors to the extent they may be entitled to such damages. In addition, to the filing of registration statements in connection with the 2007 Financing pursuant to the amendments to the 2005 and 2006 financing documents described above, we are contractually obligated to file additional registration statements at various times in the future. Because of the SEC s recent interpretation of Rule 415, we cannot offer any assurances that

we will be able to obtain the effectiveness of any registration statement or post-effective amendments that we may file.

Our outstanding indebtedness on our 2005, 2006 and 2007 Debentures imposes certain restrictions on how we conduct our business. In addition, all of our assets, including our intellectual property, are pledged to secure this indebtedness. If we fail to meet our obligations under the Debentures, our payment obligations may be accelerated and the collateral securing the debt may be sold to satisfy these obligations.

The Debentures and related agreements contain various provisions that restrict our operating flexibility. Pursuant to the agreement, we may not, among other things:

- except for certain permitted indebtedness, enter into, create, incur, assume, guarantee or suffer to exist any indebtedness for borrowed money of any kind, including but not limited to, a guarantee, on or with respect

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

to any of its property or assets now owned or hereafter acquired or any interest therein or any income or profits therefrom;

- except for certain permitted liens, enter into, create, incur, assume or suffer to exist any liens of any kind, on or with respect to any of its property or assets now owned or hereafter acquired or any interest therein or any income or profits therefrom;

- amend our certificate of incorporation, bylaws or other charter documents so as to materially and adversely affect any rights of holders of the Debentures and Warrants;

- repay, repurchase or offer to repay, repurchase or otherwise acquire more than a de minimis number of shares of our common stock or common stock equivalents;

- enter into any transaction with any of our affiliates, which would be required to be disclosed in any public filing with the Securities and Exchange Commission, unless such transaction is made on an arm s-length basis and expressly approved by a majority of our disinterested directors (even if less than a quorum otherwise required for board approval);

- pay cash dividends or distributions on any of our equity securities;

- grant certain registration rights; or

- enter into any agreement with respect to any of the foregoing.

These provisions could have important consequences for us, including (i) making it more difficult for us to obtain additional debt financing from another lender, or obtain new debt financing on terms favorable to us, (ii) causing us to use a portion of our available cash for debt repayment and service rather than other perceived needs and/or (iii) impacting our ability to take advantage of significant, perceived business opportunities.

Our obligations under the Securities Purchase Agreement are secured by substantially all of our assets. Our obligations under the security agreement, executed in connection with the 2007 Financing, with the holders of the debentures and warrants are secured by substantially all of our assets. As a result, if we default under the terms of the security agreement, such holders could foreclose on their security interest and liquidate all of our assets. This would cause operations to cease.

ITEM 3.02 Unregistered Sales of Equity Securities.

In connection with our acquisition of Mytogen described above, we issued the following securities to the former stockholders of Mytogen in exchange for all of their shares of that company: (i) 8,064,517 shares of our common stock having an aggregate value of $5,000,000 based on a per share price of $0.62, provided that, 1,209,678 of such shares were issued to the escrow agent at the closing in order to secure Mytogen s indemnification obligations, and/or (ii) warrants to purchase an aggregate of 1,500,000 shares of our common stock at an exercise price of $0.75 per share.

The issuances of the equity securities described above were made in reliance upon the exemption from registration under Section 4(2) of the Securities Act of 1933, as amended, relating to sales by an issuer not involving a public offering, and/or pursuant to the requirements of one or more of the safe harbors provided in Regulation D under the Securities Act.

ITEM 8.01 Other Events.

The Company entered into that certain Nomination Agreement dated September 20, 2007, with Anthem Ventures Fund, LP. The Company previously agreed to a nomination agreement with Anthem in August 2005. Anthem shall have the right to designate, in its sole discretion, and the Company shall nominate and appoint, a director to the Company s board of directors. The agreement terminates upon the earlier to occur of (1) certain corporate events or (2) December 31, 2009.

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

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ADVANCED CELL TECHNOLOGY, INC.

By: /s/ William M. Caldwell, IV
William M. Caldwell, IV
Chairman and Chief
Executive Officer

Dated: September 26, 2007

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