

The background of the slide is a dark blue gradient with various scientific and technological motifs. On the left, there is a cluster of hexagons, some of which are glowing with a bright blue light. To the right, there are several circular patterns, including a large, faint circular graphic that resembles a stylized 'S' or a series of concentric arcs. A network of nodes and lines is visible, suggesting a molecular or data structure. At the bottom, there is a horizontal row of rectangular shapes, possibly representing a DNA sequence or a data array.

FROST & SULLIVAN

March 2015

Strategic Analysis of AnC Bio Products and Services: Evaluating Demand

Executive Summary Prepared For
Jay Peak Biomedical Research Park L.P.

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1 INTRODUCTION

Frost & Sullivan was commissioned, as a third-party research and consulting firm, by Jay Peak Biomedical Research Park L.P., to assess and evaluate AnC Bio VT products and services in context of the marketplace; specifically, to address global market demand and opportunities. The following products and services were included in the scope of work: Twin-Pulse Life Support System (T-PLS), Carry-On Pulsatile Artificial Kidney (C-PAK), E-Liver, Stem Cell, and Cleanroom facilities. Key findings are captured in this Executive Summary, in which Frost & Sullivan concludes that AnC Bio VT products and services address significant global demand, and retain qualities of market attractiveness and competitive edge. Moreover, based upon the market analysis, the projections in the AnC Bio VT business plan and payments made for the related intellectual property rights appear reasonable.

Overview of AnC Bio Medical Devices

Treatment of heart, kidney, and liver disease incurs tremendous costs to the healthcare system. To a large extent, these diseases are treated and managed by the use of devices that assist or replace organ function. These devices are expensive and in need of improvements to their safety, efficacy, ease of use, and cost-efficiency. AnC Bio has superior scientific and engineering expertise to develop advanced organ-assistance devices that will benefit patients and the entire healthcare system. The company produces a blood pump that is in clinical use, and is developing unique devices for kidney and liver dialysis that fill growing needs. AnC Bio's organ-assist devices have many attributes that are in demand by hospitals and clinics: simple operation, rapid setup, safety, improved efficacy, small size, light weight, and cost-efficiency. Frost & Sullivan believes that AnC Bio's technology is unmatched by existing devices. The company's organ-assist products will not only be highly competitive in the global market, but will be leaders in setting new standards for the industry.

Overview of AnC Bio Stem Cell Therapy and Manufacturing Facilities

There is great demand for new stem cell therapy products, especially in the areas of cardiovascular disease and cancer. In the United States, cardiovascular disease is the leading cause of death, with 600,000 Americans dying of some form of heart disease annually. Because of Dr. Ike Lee's extensive knowledge and experience in this area of cardiovascular stem cell therapy, his 16+ years in the biomedical industry, and his leadership position with AnC Bio, the company is well positioned to provide new, leading-edge stem cell therapies for cardiovascular disease.

The largest roadblock to the advancement of the stem cell therapy industry is the lack of FDA-approved current good manufacturing practices (cGMP) cleanrooms for stem cell manufacturing: if only 20% of all late-stage stem cell therapy products (those in clinical trial phases 2/3, 3, or 4) were to reach the market within the next 2 to 5 years, there would not be enough manufacturing capacity globally to produce them. Therefore, there is great opportunity for efficient, well-designed stem cell manufacturing facilities such as that proposed by Jay Peak/AnC Bio.

Because large-scale manufacturing of stem cell products is most lucrative, Jay Peak/AnC Bio will strive to reach capacity in large-scale manufacturing as soon as possible. To attain this goal, it will be important for Jay Peak/AnC Bio to open its doors to early-stage companies that are conducting research or have technologies in early-stage clinical trials (phases 1–2), so they will grow and expand in-house and transition to the Contract Manufacturing Organization (CMO) Model for large scale manufacturing. Jay Peak/AnC Bio will attract these companies by offering high-quality contract research capabilities and manufacturing capabilities, as well as incentive packages and partnerships. This will generate customer loyalty and industry recognition for Jay Peak/AnC Bio, while ensuring long-term sustainability.

In these ways, Jay Peak/AnC Bio will attract new technology to the area and act as a biomedical technology magnet for Vermont. Support industries will become prevalent, and—most importantly—jobs will be created. These jobs will range from high-level managerial to laboratory and administrative positions. Jay Peak/AnC Bio also has strong relationships with the high schools, vocational schools, and colleges in New England and Quebec. By leveraging these relationships, people can be trained locally for jobs at the Jay Peak/AnC Bio facility.

In summary, Frost & Sullivan has determined that stem cell therapy is a large, emerging market that will require FDA-certified cGMP facilities for early- and late-stage stem cell product development and commercialization. Industry growth in the United States and abroad is limited, in part, by the lack of certified cGMP cleanroom manufacturing facilities. This shortage could provide great opportunity for Jay Peak/AnC Bio and the state of Vermont as they build one of the first leading-edge stem cell therapy manufacturing facilities in the world. In this way, the City of Newport and the surrounding areas will become a recognized hub for biomedical stem cell therapy, while Vermont residents are locally trained and subsequently retained to work in the area.

2 ANC BIO TWIN-PULSE LIFE SUPPORT SYSTEM (T-PLS)

AnC Bio produces the T-PLS which is a mechanical blood pump with unique features that are in high demand by hospitals for their cardiac surgery and extracorporeal life support programs. It acquired regulatory approval for sale in South Korea, China, and Europe and has been used in over 500 clinical cases. These unique features include: 1) compact size, 2) light weight, 3) minimal damage to blood cells, 4) physiologic pulsatile flow, 5) easy setup and operation, 6) convenient user interface, 7) preassembled disposables for quick connection in an urgent situation, 8) auto-priming for rapid use, and 9) comparatively low cost.

T-PLS is well differentiated to meet demand in the cardiac surgery market for safety and efficacy features that derive from its minimal damage to blood cells and its physiologic pumping action. Cardiac surgery programs also value blood pumps that are simple and quick to set up, and that are cost-effective. In the market for life support, T-PLS fills high demand for lightweight and compact blood pumps that are ready to use in minutes and are simple to operate. Based on the high demand for

features on which T-PLS excels and the large market size for blood pumps and consumables, Frost & Sullivan believes T-PLS is a highly attractive opportunity for investment.

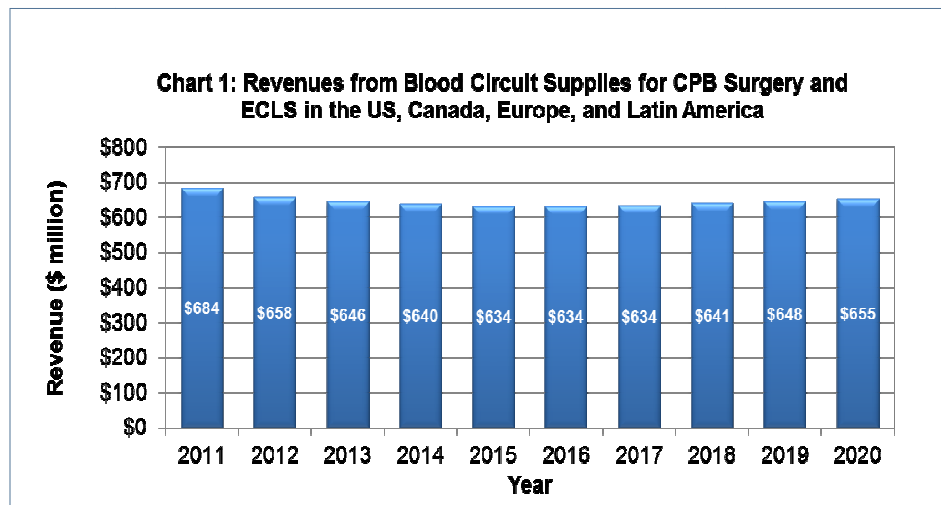
A blood pump is a mechanical device that wholly or partially substitutes the blood-pumping function of the heart. The Frost & Sullivan report focuses on extracorporeal blood pumps, which function outside the body, as opposed to implantable blood pumps. The market for extracorporeal blood pumps is mature, but there is room for new products that offer clinical and cost-saving advantages over existing blood pumps.

AnC Bio’s T-PLS is well-suited for two applications: cardiopulmonary bypass (CPB) surgery and extracorporeal life support (ECLS). The market for CPB pumps and consumables is the larger of the two, with over 800,000 CPB surgeries performed in 2014, and with 6,700 arterial CPB pumps installed in the United States, Canada, Europe, and Latin America. While the market has been declining, it is expected to stabilize by 2015.

The market for ECLS pumps is smaller, but is evolving faster. There were 2,800 ECLS procedures performed in 2014; the growth rate is 8% per year. New pumps directed specifically at the ECLS market are being introduced and are seen as having value-added differentiating features.

By 2020, total revenue from blood pumps will approach \$14 million. Revenue from blood circuit consumables will exceed \$650 million in the United States, Canada, Europe, and Latin America (see Chart 1 below).

The main driver of this market is the increasing number of patients requiring cardiac intervention. The main restraint is the development of minimally invasive treatments. However, with attributes and qualities of T-PLS, Frost & Sullivan believes AnC Bio maintains a strong competitive edge and market attractiveness.



AnC Bio’s T-PLS has important features that are in demand and competitive with other pumps. T-PLS fits many needs of the blood pump market and could compete with other products in all covered regions. T-PLS has unique features, such as its pulsatile flow, small size, and low cost, that are desired and that differentiate it from existing blood pumps.

The key attributes of blood pump systems are broad range of application, ease of transport, ease of operation, short time to set up, and low consumables cost. A comparison of several systems (Table 1 below) shows that T-PLS fulfills all these key attributes, while competing systems are more limited in fulfilling the attributes.

In terms of target customers, Frost & Sullivan recommends that T-PLS be marketed to hospitals as a means to improve patient outcomes by using pulsatile flow, reduce costs, and increase the capacity for treating ECLS

Table 1: Comparison of Blood Pump Systems on Key Product Attributes

Company	Product	Attributes				
		Broad Range of Application	Easy to Transport	Easy to Operate	Short Set-Up Time	Low Consumables Cost
AnC Bio	T-PLS	√	√	√	√	√
Sorin	S5 heart-lung machine	X	X	X	X	√
Maquet	Cardiohelp	X	√	X	√	X
Terumo	Advanced Perfusion System	X	X	X	X	√
Thoratec	Centrimag	X	√	X	X	X

Key: √ = High fulfillment of attribute
 X = Moderate fulfillment of attribute
 X = Low fulfillment of attribute

patients. Morbidity and mortality with CBP surgery can be improved; T-PLS provides pulsatile flow that contributes to this improvement. Hospitals are increasingly cost-constrained and should view T-PLS as a way to contain costs. ECLS is a growing market with a large need to reduce mortality and morbidity of the seriously ill patients who receive ECLS. Hospitals will be interested in T-PLS for its safety and efficacy, as well as its benefits in size and weight for transporting patients.

Overall, there is significant demand for innovative medical devices such as T-PLS from AnC Bio. T-PLS has value-added attributes and features that will support a compelling market offering in an industry that is projected to be worth over \$650 million globally by 2020.

3 ANC BIO CARRY-ON PULSATILE ARTIFICIAL KIDNEY (C-PAK) SYSTEM

AnC Bio is developing the C-PAK, a hemodialysis system with several features that are highly appealing to dialysis clinics, hospitals, and patients on home hemodialysis. C-PAK is much smaller and lighter than current hemodialysis systems. It uses disposable dialyzer units that are convenient and preset to a patient’s therapy. C-PAK has an emergency backup system and integrated safety sensors. The device is easy to operate through a large color touchscreen, and is capable of remote monitoring

and control. The system’s feature of pulse push/pull hemodialysis allows for simple operation compared with conventional hemodialysis. C-PAK also requires a lower volume of treatment fluid than conventional hemodialysis; a separate water treatment device can be added to further reduce the need for dialysis fluid.

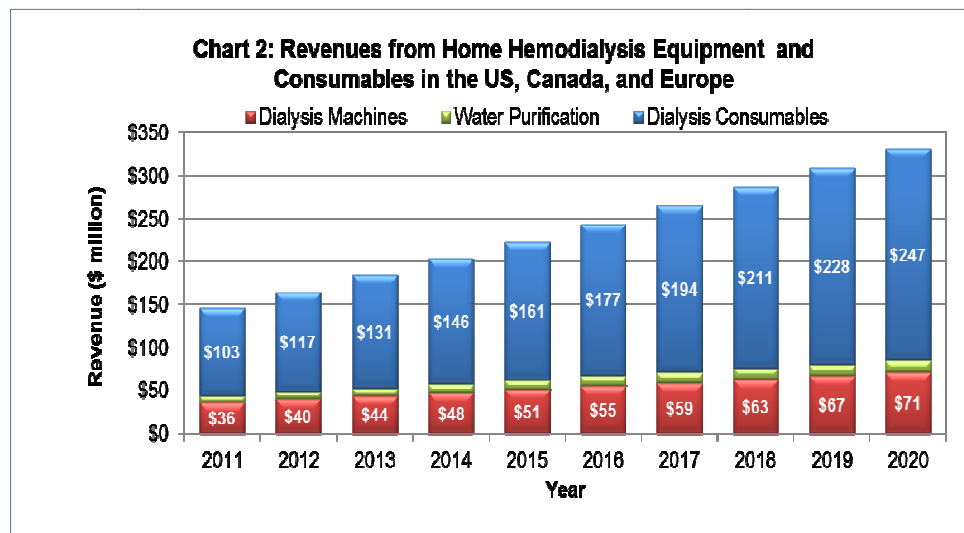
Dialysis clinics and hospitals have high demand for hemodialysis systems that reduce the costs of labor, equipment, and consumables. Features of AnC Bio’s C-PAK, such as its ease of use, remote monitoring, and low volume of dialysis fluid, help meet these demands better than current systems. The market for home hemodialysis demands small, lightweight, safe, and easy-to-use systems—features on which C-PAK also excels compared with existing systems. Frost & Sullivan believes that AnC Bio’s C-PAK has tremendous potential for rapid acceptance in the large market for hemodialysis.

Hemodialysis is a treatment for chronic kidney failure. In hemodialysis, waste solutes in blood diffuse across a semipermeable membrane (dialyzer) into a dialysis fluid (dialysate) on the other side. Hemodialysis may be performed in a dialysis center, a hospital, or in the patient’s home. In the United States, over 90% of hemodialysis patients receive treatment in dialysis centers. Frost & Sullivan estimates that total revenues for hemodialysis machines and consumables in the United States, Canada, Europe, and Latin America was \$9.4 billion in 2014, and will grow to \$12 billion by 2020. The following report focuses primarily on one segment: home hemodialysis (HHD).

The market for HHD is growing. There is room and market opportunity for new products that improve the patient experience and offer cost savings to dialysis clinics; here, C-PAK may be an attractive product offering. HHD use varies greatly by region; for example, the percentage of dialysis patients on HHD is 4% in Canada, 1.7% in the United States, and 0% in Latin America. There were 11,600 patients on HHD in the United States, Canada, and Europe in 2012, and the number was growing at 11.8% per year.

Chart 2 below shows that revenue from HHD machines is projected to reach \$71 million by 2020; from dialysis consumables, it is projected to reach \$247 million. Consumables include single-use dialyzers and dialysate solution.

HHD is mostly administered by single-payer systems, such as U.S. Medicare. Patients receive HHD training at dialysis clinics, which also arrange for the installation of the HHD machine and periodic delivery of supplies to HHD patients. Major HHD



competitors are NxStage and Fresenius. NxStage dominates the U.S. market, and is expanding market share in Europe at the expense of Fresenius. NxStage has advantages in size and ease of use. However, Frost & Sullivan believes that AnC Bio’s C-PAK could compete well in this marketplace.

AnC Bio’s C-PAK has important features that are in demand and competitive with current HHD systems. C-PAK fits many needs of the growing HHD market and could compete with other products in all covered regions. C-PAK has unique features, such as its small size and low cost, that differentiates it from existing and upcoming HHD systems.

Key attributes of dialysis systems are ease of operation, ease of transport, remote monitoring, low dialysate volume requirement, and low consumables cost. A comparison of several systems (Table 2 below) shows that AnC Bio C-PAK highly fulfills all these key attributes, while competing systems are more limited in fulfilling these attributes.

Major market drivers of HHD are convenience for the patient and higher margins for dialysis centers. Major market restraints are the burden on caregivers of providing dialysis at home five or six times per week, and managing vascular access.

Table 2: Comparison of Home Hemodialysis Systems on Key Product Attributes

Company	Product	Attributes				
		Easy to Operate	Easy to Transport	Capability for Remote Monitoring	Low Dialysate Volume	Low Cost of Consumables
AnC Bio	C-PAK	√	√	√	√	√
Fresenius	2008@ home	X	X	X	X	√
NxStage	System One	√	X	X	X	X
Baxter	Vivia	√	X	√	Not found	Not found
Quanta Fluid Solutions	Quanta SC+	√	X	X	Not found	Not found

Key: √ = High fulfillment of attribute
 X = Moderate fulfillment of attribute
 X = Low fulfillment of attribute

While C-PAK’s attributes and benefits are attractive in the marketplace, Frost & Sullivan recommends that the C-PAK be marketed to dialysis clinics to attract and keep patient volume, and to reduce operational costs. Dialysis clinics are increasingly cost-constrained and see HHD as one way to keep margins from eroding.

Because the global market demand is relatively significant, the low cost of AnC Bio’s C-PAK could be the key to opening the Latin American market for HHD, which thus far has been dormant.

4 ANC BIO E-LIVER SYSTEM

AnC Bio is developing the E-Liver hemodialysis system for treating the blood of liver failure patients. This system has several features that are highly appealing to hospitals with liver transplant programs. Currently a limited number of liver dialysis devices are available, but they are complex and costly to operate. The E-Liver removes toxins that are bound to proteins, as well as low molecular weight components. It performs plasma separation and perfusion in a single filter unit, allowing a simpler mechanism for cleansing the blood of liver failure patients than current systems. In contrast to one existing liver dialysis system, the E-Liver requires no supplementary albumin supply. Pilot studies show that liver dialysis treatment with E-Liver is highly effective at removing uremic and hepatic toxins. The system is also safe, as blood cell integrity is well maintained during dialysis with E-Liver. Treatment with E-Liver is also costs less than available devices.

The E-Liver fulfills a large need as a bridge to liver transplant, and for supporting liver function during healing or recovery. Hospital liver treatment and transplant programs have a great need for liver dialysis that is highly efficacious, simple to perform, and cost-effective. The features of AnC Bio's E-Liver, such as its high efficacy at removing toxins, its simple mechanism, low-cost filter unit, and lack of need for albumin, meet these demands better than current systems. Frost & Sullivan believes that the E-Liver fills a large void in the market for liver support, and is an attractive opportunity for further development.

Liver dialysis is the process of removing toxins from blood that are normally cleared by a healthy liver, but which accumulate when the liver is diseased, leading to the risk of death. There are two main conditions to which liver dialysis can be applied: acute liver failure (ALF), and acute-on-chronic liver failure (ACLF).

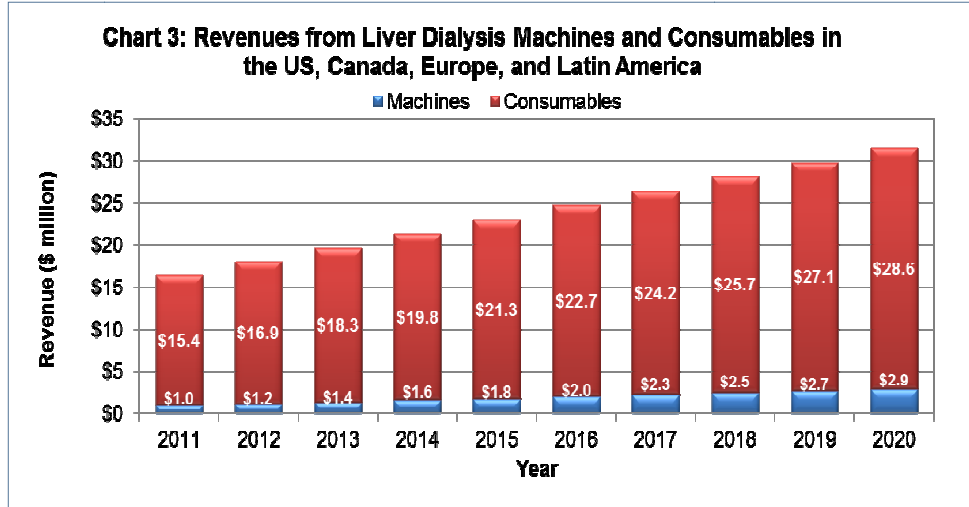
The market for liver dialysis is growing. There is room for new products with improved efficacy and that offer cost savings to hospitals. The major applications for liver dialysis are as a bridge to liver recovery in ALF and as a bridge to liver transplant in acute liver failure and ACLF.

In 2012, there were 9,750 ALF patients in the United States, Canada, Europe, and Latin America, and about 1,156 patients who received liver transplants for ACLF. There were 334 liver transplant centers in these regions.

In 2012, a total of 1,024 patients received liver dialysis in these regions; the number is growing at about 105 per year. The total number of liver dialysis machines was 97; this is growing at about 6 to 7 per year.

Revenue from the sale of liver dialysis machines is projected to reach \$2.9 million by 2020, and from liver dialysis consumables, \$28.6 million (Chart 3). Consumables typically include a set of four filters, and may include human albumin. In the related market of hemoperfusion to treat poisoning and septic shock, revenues for hemoperfusion consumables were at least \$98 million worldwide in 2014.

The major competitors in liver dialysis are the MARS and Prometheus systems. MARS comprises 88% of the total market; Prometheus is sold only in Europe. Frost & Sullivan believes that AnC Bio’s E-Liver has features that are in demand and competitive with



existing systems. E-Liver fits many needs of the growing liver dialysis market and could compete with other products in all covered regions. E-Liver’s features, such as its efficacy at filtering toxins, simple operation, and low cost, differentiate it from current liver dialysis systems.

Key attributes of liver dialysis systems are system simplicity, ease of operation, lack of albumin requirement, and low consumables cost. A comparison of three systems (Table 3 below) shows that the AnC Bio E-Liver fulfills all these key attributes, while competing systems are more limited in fulfilling the attributes.

The major market drivers of liver dialysis are clinical acceptance of its efficacy and new indications for use. Major market restraints are the shortage of donor livers for transplant and the cost of liver dialysis.

Company	Product	Attribute			
		Simple System	Easy to Operate	No Albumin Requirement	Low Consumables Cost
AnC Bio	E-Liver	✓	✓	✓	✓
Baxter/ Gambro	MARS	✗	✗	✗	✗
Fresenius	Prometheus	✗	✗	✓	✗

Key: ✓ = High fulfillment of attribute
 ✗ = Moderate fulfillment of attribute
 ✗ = Low fulfillment of attribute

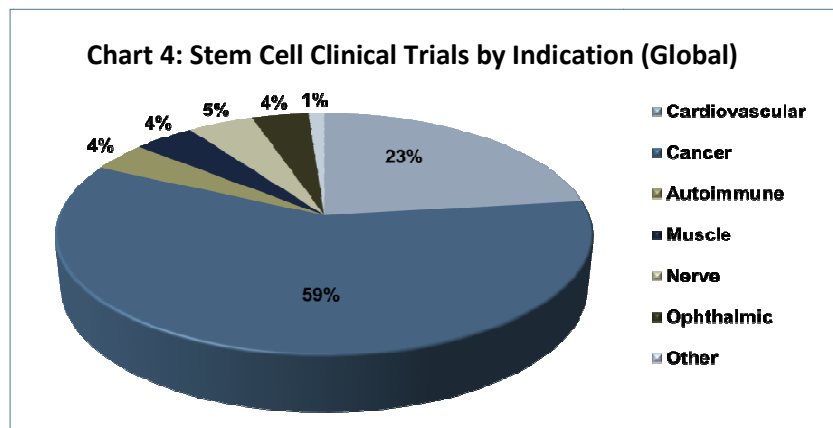
Frost & Sullivan recommends that E-Liver be marketed to hospitals as a means to improve the outcomes of patients with ALF and ACLF, and to reduce costs. Hospitals are increasingly cost-constrained and should consider E-Liver as one component of controlling costs.

The low cost of AnC Bio’s E-Liver could be the key to expanding the Latin American market for liver dialysis, which thus far remains small in spite of the existence of liver centers with experience in liver transplant and treating liver failure.

5 ANC BIO STEM CELL THERAPY SERVICES

Today, regenerative medicine aims to augment, repair, or regenerate tissue and organs damaged by disease, injury, or the natural aging process. While a vast majority of available treatments for chronic and fatal diseases can only relieve the symptoms of or delay disease progression, regenerative medicine is capable of altering the underlying disease mechanism. Regenerative medicine is composed of four market segments: cell therapy, gene therapy, tissue engineering, and small molecules and biologics. Over 60% of the regenerative medicine market is in the area of cell therapy, the majority of which is in the form of stem cell therapy.

Stem cell therapy is the use of stem cells to treat or prevent a disease or condition. Stem cells can be derived from a variety of sources including pre-implantation embryos, adult bone marrow, blood, brain, liver, intestine, skin, and fat (adipose). Stem cells can differentiate into a variety of adult cell types. Stem cells from pre-implantation embryos can differentiate into any tissue in the adult body and are called pluripotent stem cells (PS). Stem cells from cord blood and bone marrow can be induced to differentiate in to multiple cell types (although not as many as those of embryonic origin) and are called induced pluripotent stem cells (IPS). A third type of stem cell can be isolated from other adult tissues but can only differentiate into cells specific to that tissue; these are called tissue-specific stem cells.

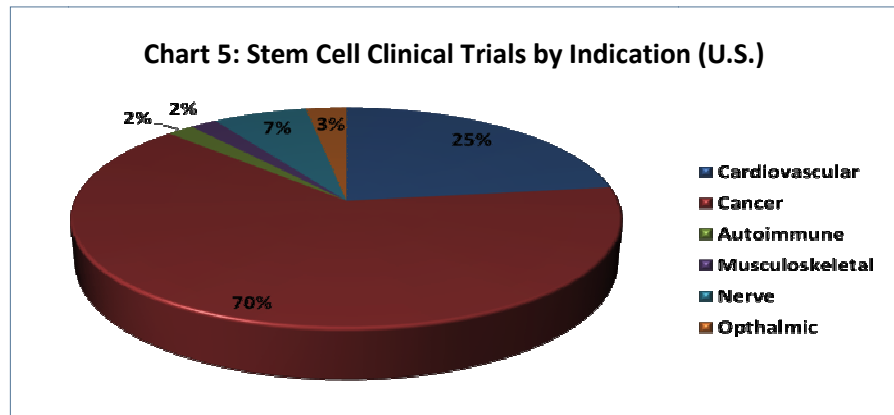


The global stem cell therapy market is new and rapidly expanding. In 2013, although only 20 stem cell products were approved by regulatory agencies, \$1.25 billion in revenue was generated with a total market value of \$6.53 billion, which is expected to grow at a compound annual growth rate (CAGR) of 13.6%. Stem cell products comprised \$3.22 billion of the market value, while the cell therapy value was \$3.31 billion.

Stem cell products are items used to create, support, or deliver stem cell therapies. Stem cell therapies are the therapeutic stem cells themselves, and/or their components, that are used to treat patients.

The global stem cell therapy market is rapidly growing and is expected to reach \$10.6 billion by 2018. This market is made up of numerous types of therapies that can be broken down by indication as shown in Chart 4.

The United States has the largest share of the stem cell therapy market and is growing faster than any other region because it has the most research and development (R&D) activities, better methods for stem cell analysis, and more clinical trials—many of which are fast-tracked



by the FDA. The United States stem cell therapy market is currently worth \$2.2 billion and is projected to grow to \$3.9 billion by 2019. Stem cell therapies, by indication, in the United States closely resemble global trends (see Chart 5).

The major strategic recommendation for AnC Bio for entering the stem cell therapy market is to continue monitoring the markets, especially in the United States and Japan. In the United States, new manufacturing strategies will rapidly evolve to meet FDA requirements while optimizing product yield. The Japanese market is most rapidly moving towards commercialization and should be observed on the following: identification of indications where commercialization success is the greatest (i.e., cancer or cardiovascular disease), cell therapies where single cell changes can be effective, therapies with greatest societal need, and technologies that may result in the largest profit margins (i.e., autologous therapies, which have a much lower profit margin than allogeneic therapies).

6 JAY PEAK/ANC BIO CLEANROOM MANUFACTURING FACILITIES

Many cardiovascular and cancer clinical trials are in phases 2–4, with many requiring consistent, reliable cGMP (cleanroom) manufacturing in cGMP-certified facilities. The advancement of the stem cell therapy industry is dependent on the availability of and the successful operation of these facilities. This becomes increasingly important when one realizes that there is no other industry in which the living cells are the product, and that all variability in cell viability and potency must be standardized and minimized during manufacturing in these cGMP facilities. To date, there are a number of small cGMP facilities in the world that are capable of producing the small numbers of stem cells required for early-stage clinical trials (phases 1-2). These small scale manufacturing facilities fit the Hotel Model where researchers and start-up companies can “visit” the facility and work with the in-house staff to produce

the desired number of cells. Facilities equipped to manufacture stem cells on a large scale basis (for late stage clinical trials or for products on the market) fit the CMO Model. When compared to the Hotel Model facilities, even fewer CMO Model facilities exist that are capable of generating the larger numbers of stem cells required for the later stage clinical trials (phases 3-4) and still fewer are equipped and certified for large scale commercialization of the new emerging stem cell therapies.

This is due, in part, to stringent cGMP requirements and the high cost of build-out followed by low return on investments during the early stages of operation. In order to reduce risk, many new centers of excellence are emerging in which state and public funds are leveraged to build, operate, and provide contract manufacturing services for stem cell therapy companies at an affordable rate. Twenty-two cGMP facilities that specify stem cell manufacturing capabilities are registered with the Association of Academic Biologics Manufacturing (AABM). The majority of these facilities only have production capabilities for small cell numbers, such as those needed for early stage clinical trials (phases 1–2); and thus, fit the Hotel Model. In contrast, the UK government has recently slotted \$90 million for a large-scale cell therapy manufacturing center to be located at The Cell Therapy Catapult in Stevenage for stem cell products that are maturing in the approval pipeline and will require scale-up manufacturing for commercialization in the near future.

As Jay Peak/ AnC Bio develops its manufacturing facility, it will be important to consider the following variables: Jay Peak/ AnC Bio's core competencies; the balance between early-stage R&D/clinical trials 1–2 (Hotel Model) and late-stage high volume manufacturing (CMO Model); the need for closed cell culture capabilities; flexibility of cGMP lab configurations; workforce education, training, attraction and retention; and issues related to transportation.

In identifying critical success attributes for stem cell manufacturing, Frost & Sullivan shows a comparison of how Jay Peak/ AnC Bio aligns with industry standards and expectations (Table 4 below). The comparison shows that Jay Peak/ AnC Bio addresses all these critical attributes. And by meeting these, Jay Peak/ AnC Bio is potentially positioned to become leaders in the Stem Cell Therapy industry.

Table 4: Alignment of Critical Attributes for Stem Cell Manufacturing Facilities		
Key Attributes for Success	Jay Peak/ AnC Bio Matches Key Attributes	Areas to be Watchful
All operations must be FDA compliant. Clients will also need FDA regulatory guidance.	Jay Peak/ AnC Bio has contracted Biologics Consulting Group, Inc., Alexandria, VA: General Electric's agency of choice for build-out & client needs.	Facility and products are FDA compliant and must be maintained and monitored at all times.
Must have a universal Quality Management System (QMS) with protected IP.	A strong QMS will be developed and implemented when the new facility is ready.	Keep costs associated QMS labor and costs low: automate as much as possible.
Hotel and CMO models differ greatly; activities must be kept separate when housed at same facility.	Jay Peak/ AnC Bio will prepare to be both the Hotel and CMO models, with initial operations focused on Hotel, followed by CMO.	Keep the Hotel Model activities separate from the CMO Model.
The market is moving from autologous to allogeneic stem cell products: most autologous production will be at the point of care.	Plans will be made to transition to allogeneic stem cell production to keep up with market demand and to take advantage of the larger profit margins that are attainable.	Be aware of market changes and new technology/ products that will assist in and reduce costs of autologous and allogeneic stem cell production.
Manufacturing is moving away from tissue culture flasks to closed system bioreactors- FDA will require it.	Jay Peak/ AnC Bio will offer both stem cell culture systems.	Be aware of when new closed culture systems and bulk large scale reactors are on-line.
Executive level expertise and availability of a skilled work force.	Key executive: Ike Lee, Ph.D., of AnC Bio; Labor force education/recruitment strategies developed, i.e., support, collaboration & training programs at local high schools, universities and colleges; Recruitment and retention packages available.	Stay focused in areas where expertise are in-house; keep labor costs as low as possible; and automate as many processes as possible.

By meeting the standards of excellence, Jay Peak/ AnC Bio will be positioned as leaders in the Stem Cell Therapy industry. Not only are they conducting the necessary studies and due diligence, they are hiring the right experts to develop ideas, construct and then operate one of the first stem cell manufacturing facilities of its kind. They are carefully considering all aspects of product development and manufacturing as they relate to the following: (a) stem cell therapy market demand that includes market size and disease type, (b) small versus large scale manufacturing requirements, (c) the Hotel Model versus the CMO Model as it relates to regulation, client needs and requirements, (d) FDA approval, compliance and regulation, (e) labor needs and work force development, and (f) quality management systems and cost control. In these ways, Jay Peak/ AnC Bio is creating a hub for biotechnology that will bring jobs and educational programs to the area, stimulate the local economy and allow Vermont residents to stay in Vermont.

In summary, stem cell therapy is an emerging market that is in the growth phase. It is driven by game-changing discoveries that show how stem cell therapy can cure life-threatening diseases such as cancer and cardiovascular, musculoskeletal, and neurological diseases. Market expansion and growth is partially hindered by the high cost of stem cell product development, manufacturing, standardization of procedures, and system validation and verification, as well as the rapidly changing regulatory environment.

While the stem cell therapy is emerging and growing rapidly as a market place worldwide, its growth will be hindered by a shortage of qualified cGMP clean room facilities that will be necessary to produce the stem cell products. By building the manufacturing facility now, Jay Peak/ AnC Bio is positioning itself to capture the market. And by launching a progressive marketing campaign and maintaining a high level of industry intelligence and market presence, Jay Peak/ AnC Bio will succeed and be recognized as global thought leaders.

7 ABOUT FROST & SULLIVAN

Frost & Sullivan, the Growth Partnership Company, works in collaboration with clients to leverage visionary innovation that addresses the global challenges and related growth opportunities that will make or break today's market participants. For more than 50 years, we have been developing growth strategies for the global 1000, emerging businesses, the public sector and the investment community.

Our Growth Partnership supports clients by addressing these opportunities and incorporating two key elements driving visionary innovation: The Integrated Value Proposition and The Partnership Infrastructure.

- **The Integrated Value Proposition** provides support to our clients throughout all phases of their journey to visionary innovation including: research, analysis, strategy, vision, innovation and implementation.
- **The Partnership Infrastructure** is entirely unique as it constructs the foundation upon which visionary innovation becomes possible. This includes our 360 Degree research, comprehensive industry coverage, career best practices as well as our global footprint of more than 40 offices.

Please note that all table and charts are sourced as the following: Frost & Sullivan, Frost & Sullivan Analysis.