



Company Profile

Pervasis Therapeutics, Inc. is a clinical stage company developing a broad portfolio of biologically active therapeutics. Building on its deep understanding of the specialized role that the endothelium plays in regulating natural healing and repair processes associated with disease, Pervasis is advancing groundbreaking new therapies to dramatically improve the outcomes of common vascular interventions, such as arteriovenous access, angioplasties, stents, and peripheral and coronary bypass grafts – the failure of which result in serious complications and a significant increase in medical costs. The company's most advanced program, Vascugel®, has demonstrated proof of concept and safety in two Phase 2 trials in patients undergoing vascular access procedures for hemodialysis. Pervasis is also applying its platform technology to develop therapies in therapeutic areas beyond vascular disease, including inflammatory disease, orthopedic injury and cancer.

Pervasis is a privately held company with funding from Flagship Ventures, Polaris Venture Partners, Highland Capital Partners and the Richter Family Fund.

Company Facts

Founded: 2004

Number of Employees: 10

Ownership: Privately-held

Funding to Date: \$46.2 million

Investors: Flagship Ventures, Polaris Venture Partners, Highland Capital Partners, Musket Research Associates, The Richter Family Fund

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About Vascugel®

Vascugel®, a novel, biologically active therapy developed using tissue-engineered allogeneic endothelium, is under investigation for enhancing blood vessel repair and promoting vascular health.

Vascugel® couples a well-characterized polymer matrix with allogeneic endothelial cells to deliver growth regulatory compounds directly to the site of vascular injury, promoting a natural healing process and preventing excessive scar tissue formation, inflammation and thrombosis. The biological activity of Vascugel® allows its application in a broad array of vascular procedures where poor medical outcomes result from intimal hyperplasia, stenosis and loss of patency at the site of intervention.

Two Phase 2 clinical studies for Vascugel® as a concurrent therapy with arteriovenous access procedures in patients with end-stage renal disease have been successfully completed. In these studies, patients treated with Vascugel had fewer interventions, thrombotic events and complications than placebo-treated patients.

In May 2009, Vascugel® received an Orphan Drug designation from the U.S. Food and Drug Administration for the prevention of arteriovenous fistula or arteriovenous graft failure in patients with end-stage renal disease.

In January 2010, Pervasis reached an agreement with the FDA on the design of a pivotal Phase 3 clinical trial for Vascugel. The agreement was made under the FDA's Special Protocol Assessment (SPA) procedure. Pervasis expects to initiate the Phase 3 study in 2010.

About PVS-10200

Pervasis has developed additional polymer formulations that leverage the same endothelial technology platform as Vascugel®. The new polymer formulation, PVS-10200, enables administration of tissue-engineered allogeneic endothelial cells as an injection at the time of minimally invasive percutaneous vascular interventions, such as angioplasty and stent placement. PVS-10200 has demonstrated promising results in preclinical studies.

In April 2010, Pervasis initiated a Phase 1/2 clinical study to explore the potential of PVS-10200 to prevent restenosis in patients who undergo an angioplasty and stent procedure for the treatment of PAD. Primary endpoints for the study include safety and the impact of PVS-10200 on the incidence of major adverse events. Initial results from the Phase 1/2 study are expected at the end of 2010.



About PVS-30200

PVS-30200 is a novel, cell-based approach being developed by Pervasis to target and regulate cell stroma (the tumor environment or “ecosystem” that is comprised of various supporting cell types distinct from cancer cells) in order to prevent key processes that play a role in advancing solid tumor growth and metastasis.

Breakthrough research conducted at the Massachusetts Institute of Technology (MIT) and published recently in *Science Translational Medicine*¹, suggests that, in the tumor setting, quiescent endothelial cells are tumor-suppressive and slow the proliferation and invasiveness of cancer cells (as studied in culture and in animals), while disruption of the endothelial cells eliminates their ability to inhibit these actions that cause metastasis. Introducing exogenous functional, healthy endothelial cells to the stromal area can restore homeostasis.

PVS-30200 utilizes Pervasis' proprietary implantable material comprised of healthy allogeneic endothelial cells embedded in a polymer matrix that is delivered locally at the time of tumor excision to prevent cell-proliferation, inflammation and angiogenesis.

Pervasis has entered into an exclusive patent license agreement with MIT for all discovery and development activities associated with cellular implants for cancer diagnosis, prognosis and treatment. Supportive evidence from multiple preclinical studies demonstrates the powerful anti-angiogenic, anti-proliferative and anti-inflammatory properties of this endothelial cell-based approach in the presence of various solid tumor cancers, such as brain, lung, breast and prostate.

¹ J. W. Franses, A. B. Baker, V. C. Chitalia, E. R. Edelman, Stromal Endothelial Cells Directly Influence Cancer Progression. *Sci. Transl. Med.* 3, 66ra5 (2011).



Executive Leadership

Frederic Chereau
President & Chief Executive Officer

Mr. Chereau assumed the role of President and Chief Operating Office at Pervasis Therapeutics in September 2008. Prior to Pervasis, Mr. Chereau was the Vice President and General Manager of Genzyme Cardiovascular, a business unit of Genzyme Corporation. As VP and General Manager, Mr. Chereau led teams focusing on commercialization of a hypercholesterolemia product (Cholestagel), development of a late clinical stage gene therapy program in Peripheral Arterial Disease, and a broad range of business development activities. In addition, Mr. Chereau served as the Chief Operating Officer of MG Biotherapeutics LLC, a Genzyme and Medtronic joint-venture formed to develop cellular therapies for cardiac repair.

From 1999 to 2005, Mr. Chereau held various marketing and business development positions within Genzyme with growing responsibilities in France and Europe. During this time, he was appointed as CEO of Myosix SA, a cell therapy company based in France with an ongoing close relationship with Genzyme Cardiovascular's cell therapy programs. He relocated to the United States in 2005 and was promoted to Vice President and General Manager of Cardiovascular Business Unit in November 2006. Prior to Genzyme, Mr. Chereau started his career in sales and product management for a French medical device retail company in the hemodialysis and blood transfusion field.

In addition to Pervasis, Mr. Chereau also serves as a member of the board of directors of the French-American Chamber of Commerce New England Chapter (FACCNE) and is a member of the Comite Strategique d'Orientation at La Rochelle Business School.

Mr. Chereau holds a B.S. in Physics from Paris University, completed graduate studies at the La Rochelle Business School and received an M.B.A. from INSEAD.

Helen Marie Nugent, Ph.D.
Co-Founder and Vice President, Research and Development

Dr. Nugent is a Founder and Vice President, Research and Development, at Pervasis Therapeutics and also holds a Research Affiliate position in the Harvard-MIT Division of Health Sciences and Technology. Dr. Nugent received a B.S. degree in chemistry from Merrimack College and both M.A. and Ph.D. degrees in Organic Chemistry from Brandeis University. Her doctoral thesis concentrated on the synthesis of novel organometallic polymers. She continued her work in material science by completing one-year fellow ship at the Institute for Polymers and Organic Solids at the University of California, Santa Barbara. Dr. Nugent joined MIT as a post doctoral fellow and performed research on tissue engineered endothelial cells, which resulted in numerous peer-reviewed publications and abstract presentations.

Dr. Nugent has more than 8 years experience in the biotechnology industry directing and performing critical research and developmental work and over 10 years experience in vascular and endothelial



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biology. She previously held positions at Reprogenesis, Inc. and its successor; Curis, Inc. Dr. Nugent has been the recipient of a National Science Foundation Research Fellowship and served as the Principal Investigator on a National Institutes of Standards and Technology Advanced Technology Program Award.

Jack Harvey, M.S. Director, Manufacturing

Mr. Harvey joined Pervasis Therapeutics in December 2005 and serves as Director, Manufacturing. Mr. Harvey oversees the manufacturing of Vascugel[®] for clinical evaluation and the development and optimization of the manufacturing process. Mr. Harvey has over 20 years of experience in the development and manufacturing of Cell Therapy/Tissue Engineering products. He has held positions with technical and organizational leadership responsibilities, supporting multiple INDs covering therapies in Phase I-II clinical trials. Mr. Harvey participated in the development of numerous products from bench scale processes through manufacturing for Phase II human clinical trials at BioHybrid Technologies, Cyto Therapeutics, and Bioheart. During his career he has developed a broad range of expertise in process/product development, and manufacturing for cell and tissue based products. Mr. Harvey is a graduate from Harvard University and earned a Master's degree in Public Health from Boston University.

Margaret E. O'Toole Director, Business Administration

Ms. O'Toole joined Pervasis Therapeutics in March 2005 and serves as Director, Business Administration. She was initially brought on board to establish the company infrastructure and is now responsible for business management and daily operations. Her responsibilities include human resources, finance, public relations, and website development. Ms. O'Toole has over 14 years of experience in business start-ups ranging from hi-tech engineering to magazine publishing. Prior to Pervasis, she was the Operations Manager for Reputation Technologies; a Massachusetts based hi-tech start-up acquired by Security Source, Inc. Ms. O'Toole previously held management positions in corporate communications, marketing, and proposal management with Synetics, Inc.; acquired by ACS, Inc., and Elephant Engineering; acquired by Syntronics, LLC. Ms. O'Toole was the Editorial Director of Shaadi Style Magazine and a marketing consultant for The Wonder Factory, a Virginia based children's museum. Ms. O'Toole received her B.A. in Literature from Carnegie Mellon University.



Latest Press Releases

Pervasis Therapeutics Announces Positive Preclinical Study Data of Novel Cell Therapy for Treatment of Solid Tumors

PVS-30200 Demonstrates Significant Inhibition of Primary Tumor Growth and Distant Chest Metastases in Animal Model of Prostate Cancer

Orlando, Florida – April 5, 2011 – Pervasis Therapeutics, Inc. today announced preclinical data showing positive effects of PVS-30200, the company's investigational cell therapy for the treatment of solid tumors, on controlling tumor growth and inhibiting metastases in an animal model of prostate cancer. The data were presented in a late-breaking oral presentation at the American Association for Cancer Research (AACR) 102nd Annual Meeting in Orlando.

PVS-30200, which utilizes Pervasis' proprietary implantable material comprised of healthy allogeneic (donor) endothelial cells embedded in a polymer matrix, is designed to treat tumors locally to regulate key processes involved in tumor growth and metastasis in order to prevent the spread of cancer to secondary sites in the body. The well-studied patented technology on which PVS-30200 is founded has a proven safety profile as demonstrated by data from six clinical studies in the area of vascular repair.

Joseph Franes, from the Harvard Medical School/Massachusetts Institute of Technology (MIT) Division of Health Sciences and Technology, and the lead author of the abstract, "*A first-in-class novel therapy (PVS-30200) for the treatment and prevention of metastatic cancer by regulating the tumor microenvironment,*" gave the presentation at AACR. The preclinical data demonstrated PVS-30200's ability to promote homeostasis and act as a paracrine regulator of the tumor and its microenvironment, releasing factors which signal to nearby cells and regulate key processes, including cell proliferation and inflammation, thereby preventing tumor growth, and limiting cancer invasion and metastasis.

In the study, spontaneously metastasizing prostate (PC-3M) luciferase-expressing cancer cells were injected into the prostate of male mice. 14 days after tumor inoculation, PVS-30200 was injected into the area surrounding the tumor. Progression of the primary tumor and chest metastases were monitored using bioluminescent *in vivo* imaging. Twenty-nine days after tumor inoculation and 15 days post PVS-30200 treatment, significant inhibition of both primary tumor growth and distant chest metastases was observed ($p < 0.05$ for both).

"We are highly encouraged by today's presentation and these findings, as they represent an important step in demonstrating the promising therapeutic potential of PVS-30200," said Helen Marie Nugent, PhD, Co-Founder and Vice President, Research and Development at Pervasis and a co-author of the AACR abstract. "We recognize the tremendous need for safer, more



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effective cancer treatments and, as such, will continue to aggressively pursue our development program for PVS-30200.”

A novel cell therapy approach, PVS-30200’s use of allogeneic cells, as opposed to autologous cells, enables “off the shelf” administration, eliminating the challenging logistical processes that are involved with the use of autologous cells. Traditional injection methods often result in poor cell survival and limited cell integration into host tissue. Conversely, because PVS-30200 contains cells embedded in a polymer matrix suspension for delivery, cell viability and function are preserved; the quiescent nature of the embedded endothelial cells is maintained while allowing for minimally invasive delivery of therapeutic tissue-engineered cells.

Research conducted by Mr. Franses under the supervision of Elazer Edelman, MD, PhD, Professor of Health Sciences and Technology at MIT and Professor of Medicine at Harvard Medical School, serves as the cornerstone of Pervasis’ oncology program. Pervasis has an exclusive patent license agreement with MIT for all discovery and development activities associated with cellular implants for cancer diagnosis, prognosis and treatment.

The Role of Endothelial Cells in the Tumor Microenvironment

Endothelial cells, which line the interior surface of every blood vessel in the body, are critical to tissue repair and health, and have a well-understood role in regulating many of the body’s healing processes, including those associated with vascular repair. Endothelial cells work as the body’s “police force” – helping maintain homeostasis, and control cells under a range of pathologic stresses. In January, the MIT researchers reported in the journal *Science Translational Medicine*² data suggesting that, in the tumor microenvironment, quiescent endothelial cells are tumor-suppressive and slow the proliferation and invasiveness of cancer cells (as studied in culture and in animals), while disruption of the endothelial cells eliminates their ability to inhibit these actions that cause metastasis. Introducing exogenous functional, healthy endothelial cells to the stromal area can restore homeostasis.

Pervasis, a clinical stage company based in Cambridge, Mass., is focused on developing breakthrough endothelial cell-based therapies. In addition to oncology, the company’s other areas of clinical investigation include improving outcomes following common vascular surgical and interventional procedures, such as hemodialysis access, angioplasties, stents and peripheral and coronary bypass grafts—the failures of which result in serious complications and a significant increase in medical costs.

² J. W. Franses, A. B. Baker, V. C. Chitalia, E. R. Edelman, Stromal Endothelial Cells Directly Influence Cancer Progression. *Sci. Transl. Med.* 3, 66ra5 (2011).



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The company's most advanced program, Vascugel®, has demonstrated proof of concept and safety in two Phase 2 trials in patients undergoing arteriovenous access procedures for hemodialysis. In 2010, Pervasis announced that it had reached an agreement with the U.S. Food and Drug Administration (FDA) for its Phase 3 clinical trial of Vascugel® under the FDA's Special Protocol Assessment (SPA) procedure. Through the SPA procedure, FDA formalized its agreement that the design of the Phase 3 trial was acceptable to support a regulatory submission seeking new drug approval.

About Pervasis

Pervasis Therapeutics, Inc. is a clinical stage company that is developing groundbreaking endothelial cell-based therapies designed to regulate the body's natural healing and repair processes in various critical therapeutic areas. The company has initially focused on developing therapies to improve the outcomes of common vascular interventions, such as arteriovenous access, angioplasties, stent placements, and peripheral and coronary bypass grafts – the failure of which result in serious complications and a significant increase in medical costs. The company's lead program, Vascugel®, has demonstrated proof of concept and safety in two Phase 2 clinical trials. Pervasis is also applying its endothelial cell-based platform technology to develop an oncology therapy focused on preventing solid tumor growth, cancer recurrence and metastatic disease, as well as products for inflammatory disease and orthopedic injury.

Pervasis is a privately held company with funding from Flagship Ventures, Polaris Venture Partners, Highland Capital Partners and the Richter Family Fund. For more information, please visit www.pervasistx.com.

This news release contains certain forward-looking statements that involve risks and uncertainties. Such statements are only predictions and the company's actual results may differ materially from those anticipated in these forward-looking statements. Factors that may cause such differences include the timing of clinical trials, the risk that products that appeared promising in early research and clinical trials do not demonstrate safety or efficacy in clinical trials and the risk that the company will not obtain approval to market its products.



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Pervasis Therapeutics Announces Late-Breaking Oral Presentation at Association for Cancer Research Annual Meeting

Presentation to Detail Findings of First-in-Class Cell Therapy Designed to Treat and Prevent Metastatic Cancer

Cambridge, Mass. – March 22, 2011 – Pervasis Therapeutics, Inc. today announced that researchers will present pre-clinical data related to PVS-30200, the company's investigational cell therapy for the treatment of solid tumors, at a late-breaking oral presentation at the upcoming American Association for Cancer Research (AACR) 102nd Annual Meeting 2011 in Orlando, Florida.

PVS-30200, which utilizes Pervasis' proprietary implantable material comprised of healthy allogeneic (donor) endothelial cells embedded in a polymer matrix, is designed to be administered locally to regulate processes involved in tumor growth and metastasis, including cell-proliferation, inflammation and invasion, in order to prevent the spread of cancer to secondary sites in the body. The well-studied patented technology on which PVS-30200 is founded has a proven safety profile as demonstrated by data from six clinical studies in the area of vascular repair.

Joseph Franes, from the Massachusetts Institute of Technology's (MIT) Division of Health Sciences and Technology, is the lead author of the abstract titled, "*A first-in-class novel therapy (PVS-30200) for the treatment and prevention of metastatic cancer by regulating the tumor microenvironment,*" and will present the data at a Late-Breaking Research Session on Cancer Therapeutics and Epidemiology beginning at 3:00 p.m. on Tuesday, April 5, 2011 in Room W415 B/C (Vallencia Ballroom) at the Orange County Convention Center.

"We look forward to presenting PVS-30200 data at AACR and to having an opportunity to communicate the potential for this therapy to the oncology community," said Helen Marie Nugent, PhD, Co-Founder and Vice President, Research and Development at Pervasis and a co-author of the AACR abstract. "We are moving forward aggressively with our development program for PVS-30200 in order to deliver a safer, more effective treatment for solid tumors, preventing cancer recurrence and improving outcomes for cancer patients."

Research conducted by Mr. Franes under the supervision of Elazer Edelman, MD, PhD, Professor of Health Sciences and Technology at MIT and Professor of Medicine at Harvard Medical School, serves as the cornerstone of Pervasis' oncology program. Pervasis has an exclusive patent license agreement with MIT for all discovery and development activities associated with cellular implants for cancer diagnosis, prognosis and treatment.

The Role of Endothelial Cells in the Tumor Microenvironment

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Endothelial cells, which line the interior surface of every blood vessel in the body, are critical to tissue repair and health, and have a well-understood role in regulating many of the body's healing processes, including those associated with vascular repair. Endothelial cells work as the body's "police force" – helping maintain homeostasis and control cells under a range of pathologic stresses. In January, the MIT researchers reported in the journal *Science Translational Medicine*³ data suggesting that, in the tumor microenvironment, quiescent endothelial cells are tumor-suppressive and slow the proliferation and invasiveness of cancer cells (as studied in culture and in animals), while disruption of the endothelial cells eliminates their ability to inhibit these actions that cause metastasis. Introducing exogenous functional, healthy endothelial cells to the stromal area can restore homeostasis.

Pervasis, a clinical stage company based in Cambridge, Mass., is focused on developing breakthrough endothelial cell-based therapies. The company's other areas of clinical investigation include improving outcomes following common vascular surgical and interventional procedures, such as hemodialysis access, angioplasties, stents and peripheral and coronary bypass grafts—the failures of which result in serious complications and a significant increase in medical costs.

The company's most advanced program, Vascugel®, has demonstrated proof of concept and safety in two Phase 2 trials in patients undergoing arteriovenous access procedures for hemodialysis. In 2010, Pervasis announced that it had reached an agreement with the U.S. Food and Drug Administration (FDA) for its Phase 3 clinical trial of Vascugel® under the FDA's Special Protocol Assessment (SPA) procedure. Through the SPA procedure, FDA formalized its agreement that the design of the Phase 3 trial was acceptable to support a regulatory submission seeking new drug approval.

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³ J. W. Franses, A. B. Baker, V. C. Chitalia, E. R. Edelman, Stromal Endothelial Cells Directly Influence Cancer Progression. *Sci. Transl. Med.* 3, 66ra5 (2011).



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Pervasis Receives Orphan Drug Designation in Europe for Vascugel® to Prevent Arteriovenous Access Failure in Patients Undergoing Hemodialysis

Cell-Based Therapy Aims to Regulate the Body's Healing Response, Promoting Vascular Repair, Reducing the Need for Repeat Surgical Procedures and Improving Patient Outcomes

Cambridge, Mass., March 1, 2011 — Pervasis Therapeutics, Inc. announced today that the European Commission (EC) has granted Orphan Drug Designation for Vascugel® for the prevention of hemodialysis vascular access failure in patients with end stage renal disease (ESRD). The designation follows a positive opinion from The Committee for Orphan Medicinal Products (COMP) within the European Medicines Agency (EMA) earlier this year.

Vascugel is a novel endothelial cell-based therapy that aims to regulate the body's healing response following surgical interventions to create vascular access which are necessary for ESRD patients undergoing hemodialysis. By promoting and enhancing vascular repair, Vascugel reduces the need for repeat surgical interventions and improves overall patient outcomes.

ESRD is an advanced and irreversible condition treated mainly by hemodialysis or kidney transplantation. It is estimated that more than 250,000 ESRD patients in the EU receive hemodialysis, a blood purification therapy designed to replace critical kidney functions – such as filtering waste.

Orphan Drug Designation by the EC provides regulatory and financial incentives for companies to develop and market therapies that treat a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union (EU). In addition to a 10-year period of marketing exclusivity in the EU after product approval, Orphan Drug Designation provides companies with scientific advice and regulatory assistance from the EMA during the product development phase, direct access to centralized marketing authorization, as well as reductions in certain fees.

“We are committed to bringing Vascugel to patients with end stage renal disease who currently must endure serious complications and repeat surgical procedures so they can continue to receive life-saving hemodialysis treatment,” Frederic Chereau, president and chief executive officer of Pervasis. “Receiving Orphan Drug Designation in the EU is an important step, as it will help to advance the development process, and enhance our ability to deliver our novel cell-based therapeutic approach to address this significant unmet medical need.”

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Vascugel has demonstrated proof of concept in two Phase 2 clinical trials involving patients with ESRD who require a permanent arteriovenous (AV) access in order to undergo hemodialysis. In these trials, Vascugel exhibited an excellent safety profile, and encouraging efficacy trends were observed, including improved duration of patency (or unimpeded blood flow) and a delay in time to first intervention as compared to placebo.

In 2009, Pervasis received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for Vascugel in patients with ESRD. Pervasis announced last month that the FDA had granted Fast Track review status for Vascugel. Last year, Pervasis reached an agreement with the FDA for a Phase 3 clinical trial of Vascugel under the Agency's Special Protocol Assessment (SPA) procedure, whereby FDA formalized its agreement that the design of the Phase 3 trial was acceptable to support a regulatory submission seeking new drug approval.

Failure of Hemodialysis Access Points Leads to Poor Outcomes

During hemodialysis, blood is removed from the body, filtered through a dialyzer, or artificial kidney, and then returned to the body. Patients must undergo a surgical intervention to create a vascular access that enables blood to flow from the body to the dialyzer and back to the body. AV fistulae (created by directly joining an artery and vein) and AV grafts (created using a synthetic tube to join an artery and vein) are the two primary types of hemodialysis access.

Due to an inflammatory cascade triggered by surgical intervention, the vascular access often has difficulty healing, and quickly become unusable or clot rapidly, prompting the need for additional, recurring surgeries to create a new access which can lead to multiple complications. Up to 60 percent of all arteriovenous (AV) grafts require re-intervention after one year.^{4,5} AV access failure is the most common reason for hospitalization among hemodialysis patients and can lead to anemia, infection, weight loss, jaundice, prolonged bleeding, and other serious complications.⁶

Vascugel® – Combating Inflammation and Promoting Healing

Pervasis' novel approach to cell therapy uses adult-differentiated allogeneic endothelial cells (donor endothelial cells with a highly targeted biologic function) embedded in a polymer matrix to enhance the body's natural healing response. The endothelium is the thin layer of cells that

⁴ Dixon et al. DAC Study Group. Effect of dipyridamole plus aspirin on hemodialysis graft patency. *N Engl J Med.* 2009; 360: 2191-2201.

⁵ Hayashi et al. Vascular access for hemodialysis. *Nat Clin Pract Nephrol* 2006; 2: 504-513

⁶ Castner D. Recommendations for tracking arteriovenous access complications using a charting-by-exception model. *Anna Journal*, 1998; 25(4): 393-396.



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lines the interior surface of blood vessels in the body. Endothelial cells are critical to tissue repair and health, and have a well-understood role in regulating many of the body's healing processes, including those associated with vascular repair.

Vascugel, which utilizes Pervasis' patented endothelial cell-based platform, is placed on the outside of the blood vessel at the AV access site during the surgical intervention to create the access. The endothelial formulation in Vascugel secrete several factors that combat inflammation and promote proper vascular healing, reducing thrombosis (or clotting) and the formation of intimal hyperplasia, or a thickening of the blood vessel wall in response to injury. After approximately four to eight weeks, Vascugel is safely resorbed by the body.

Pervasis' other areas of clinical investigation include improving outcomes in patients with peripheral artery disease (PAD) following surgical procedures such as percutaneous transluminal angioplasties (PTAs) with stenting, the failures of which result in serious complications and a significant increase in medical costs. Earlier this year, Pervasis announced it has also embarked on an oncology development program using its proprietary endothelial cell-based platform to prevent solid tumor growth, cancer recurrence and metastatic disease.

About Pervasis

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promising in early research and clinical trials do not demonstrate safety or efficacy in clinical trials and the risk that the company will not obtain approval to market its products.



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Pervasis Receives FDA Fast Track Status for Vascugel® to Prevent Arteriovenous Access Failure in Patients Undergoing Hemodialysis

Novel Cell-Based Therapy Addresses Serious Unmet Medical Need, Aims to Reduce Need for Repeat Surgical Procedures and Improve Patient Outcomes

Cambridge, Mass., February 8, 2011 — Pervasis Therapeutics announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track review status for Vascugel® for the prevention of hemodialysis access failure in patients with end stage renal disease (ESRD).

Vascugel, a novel endothelial cell-based therapy and Pervasis' lead development program, aims to regulate the body's healing response following surgical interventions to create vascular access points which are necessary for ESRD patients undergoing hemodialysis, reducing the need for repeat surgical interventions and improving overall patient outcomes.

FDA established Fast Track to facilitate the development and accelerate the pre-market review of treatments for serious and life-threatening conditions, so that these products can reach approval more rapidly. To receive Fast Track designation, a product must address a serious unmet medical condition, and be supported by strong results from pre-clinical or clinical testing demonstrating the product potential.

Vascugel has demonstrated clinical proof of concept in two Phase 2 clinical trials involving patients with ESRD who require a permanent arteriovenous (AV) access for hemodialysis. In these trials, Vascugel exhibited an excellent safety profile and encouraging efficacy trends were observed, including improved duration of patency (or unimpeded blood flow) and a delay in time to first intervention as compared to placebo.

“The fact that these very sick patients must endure serious complications and repeat surgical procedures so that they can continue undergoing hemodialysis represents a significant unmet medical need—one that Vascugel is uniquely able to address,” stated Frederic Chereau, president and CEO of Pervasis. “Fast Track designation from the FDA further validates Vascugel's potential as a safe and effective therapy for patients with end stage renal disease, and will help accelerate the pace by which we can develop and deliver this potentially transformational cell-based therapy to improve patient outcomes.”

In May 2009, Pervasis received Orphan Drug Designation from the FDA for Vascugel in patients with ESRD. Last year, Pervasis announced that it had reached an agreement with the FDA for a Phase 3 clinical trial of Vascugel under the Agency's Special Protocol Assessment (SPA) procedure. Through the SPA procedure, FDA formalized its agreement that the design of the Phase 3 trial was acceptable to support a regulatory submission seeking new drug approval. Pervasis is also awaiting official Orphan Drug Designation from the European Medicines

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Agency (EMA) after receiving a positive opinion on its application from The Committee for Orphan Medicinal Products (COMP) late last year.

Failure of Hemodialysis Access Points Leads to Poor Outcomes

ESRD is an advanced and irreversible condition treated mainly by hemodialysis or kidney transplantation. It is estimated more than 350,000 Americans with ESRD receive hemodialysis, a blood purification therapy designed to replace critical kidney functions – such as filtering waste.

During hemodialysis, blood is removed from the body, filtered through a dialyzer, or artificial kidney, and then returned to the body. Patients must undergo a surgical intervention to create a vascular access point that enables blood to flow from the body to the dialyzer and back to the body. AV fistulae (created by directly joining an artery and vein) and AV grafts (created using a synthetic tube to join an artery and vein) are the two primary types of hemodialysis access points.

Due to an inflammatory cascade triggered by surgical intervention, these vascular access points often have difficulty healing, and quickly become unusable or clot rapidly, prompting the need for additional, recurring surgeries to create new access points and also leading to multiple complications. Up to 60 percent of all arteriovenous (AV) grafts require re-intervention after one year.^{7, 8} AV access failure is the most common reason for hospitalization among hemodialysis patients and can lead to anemia, infection, weight loss, jaundice, prolonged bleeding, and other serious complications.⁹

Vascugel – Combating Inflammation and Promoting Healing

Pervasis' novel approach to cell therapy uses adult-differentiated allogeneic endothelial cells (donor endothelial cells with a highly targeted biologic function) embedded in a patented polymer matrix to enhance the body's natural healing response. The endothelium is the thin layer of cells that lines the interior surface of blood vessels in the body. Endothelial cells are critical to tissue repair and health, and have a well-understood role in regulating many of the body's healing processes, including those associated with vascular repair.

⁷ Dixon et al. DAC Study Group. Effect of dipyridamole plus aspirin on hemodialysis graft patency. *N Engl J Med.* 2009; 360: 2191-2201.

⁸ Hayashi et al. Vascular access for hemodialysis. *Nat Clin Pract Nephrol* 2006; 2: 504-513

⁹ Castner D. Recommendations for tracking arteriovenous access complications using a charting-by-exception model. *Anna Journal*, 1998; 25(4): 393-396.



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Vascugel, which utilizes Pervasis' patented endothelial cell-based platform, is placed on the outside of the blood vessel at the AV access site during the surgical intervention to create the AV access point. The endothelial formulations in Vascugel secrete several factors that combat inflammation and promote proper vascular healing, reducing thrombosis (or clotting) and the formation of intimal hyperplasia, or a thickening of the blood vessel wall in response to injury. After approximately four to eight weeks, Vascugel is safely resorbed by the body.

The company's other areas of clinical investigation include improving outcomes in patients with peripheral artery disease (PAD) following surgical procedures such as percutaneous transluminal angioplasties (PTAs) with stenting, the failures of which result in serious complications and a significant increase in medical costs. Last month, Pervasis announced it has also embarked on an oncology development program using its proprietary endothelial cell-based platform to prevent solid tumor growth, cancer recurrence and metastatic disease.

About Pervasis

Pervasis Therapeutics, Inc. is a clinical stage company developing a broad portfolio of biologically active therapeutics. Building on its deep understanding of the specialized role that the endothelium plays in regulating natural healing and repair processes associated with disease, Pervasis is advancing groundbreaking new therapies to dramatically improve the outcomes of common vascular interventions, such as arteriovenous access, angioplasties, stents, and peripheral and coronary bypass grafts – the failure of which result in serious complications and a significant increase in medical costs. The company's most advanced program, Vascugel[®], has demonstrated proof of concept and safety in two Phase 2 trials in patients undergoing vascular access for hemodialysis. In addition, Pervasis is pursuing a cell-based oncology program focused on targeting and regulating cell stroma in order to prevent key processes that play a role in advancing solid tumor growth and survival. Pervasis is also applying its platform technology to develop products in other key therapeutic areas including inflammatory disease and orthopedic injury.

Pervasis is a privately held company with funding from Flagship Ventures, Polaris Venture Partners, Highland Capital Partners and the Richter Family Fund. For more information, please visit www.pervasistx.com.

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such differences include the timing of clinical trials, the risk that products that appeared promising in early research and clinical trials do not demonstrate safety or efficacy in clinical trials and the risk that the company will not obtain approval to market its products.



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Pervasis to Present Interim Data from Phase 1/2 Clinical Study of Novel Cell Therapy Targeting Peripheral Artery Disease at International Conference on Cell Therapy for Cardiovascular Diseases

-- Initial Study Results Include Safety, Feasibility and Efficacy of PVS-10200 in Prevention of Restenosis Following Stent and Angioplasty Procedure in Superficial Femoral Artery --

Cambridge, Mass., January 20, 2011 — Pervasis Therapeutics, Inc. today announced it will present interim data from the company's Phase 1/2 clinical study of PVS-10200, an investigational cell-based therapy under development to prevent restenosis in patients with peripheral arterial disease (PAD) who undergo an angioplasty and stent procedure in the superficial femoral artery. Jean-Marc Alsac, MD, Associate-Faculty in Vascular Surgery, Department of Cardiovascular Surgery, Hôpital Européen Georges Pompidou, Paris, and principal investigator of the study, will present the findings at the Sixth Annual International Conference on Cell Therapy for Cardiovascular Disease (IC3D) today in New York City.

Dr. Alsac will report initial 6-month data from the open-label dose escalation study designed to evaluate the safety, feasibility and impact of PVS-10200 on the incidence of major adverse events. Secondary endpoints include the rates of target lesion revascularization, primary patency and restenosis. In June 2010, Pervasis announced the first cohort of patients had been fully enrolled in the study. Enrollment in a second cohort is ongoing. The study is being conducted at Hôpital Européen Georges Pompidou, and two other hospitals in France, Hôpital Bichat and Centre Hospitalier Universitaire d'Amiens.

"Although most revascularization procedures of the superficial femoral artery have high initial success rates, restenosis is a common occurrence within a year after surgery, leading to poor outcomes and the need for repeat procedures," said Dr. Alsac. "I am highly encouraged by the initial findings of the study. The low rate and nature of adverse events reported thus far demonstrate the potential of PVS-10200 as a safe, viable and minimally invasive option to treat vascular injury and improve outcomes for patients."

Pervasis is a clinical stage company focused on developing breakthrough therapies with the potential to improve outcomes following common vascular surgical and interventional procedures, such as arteriovenous access, angioplasties, stents and peripheral and coronary bypass grafts—the failure of which result in serious complications and a significant increase in medical costs. There are no currently approved therapies that directly target the underlying physiological processes leading to serious vascular complications, including inflammation, thrombosis (the formation of a blood clot inside a blood vessel) and restenosis (the re-narrowing of a coronary artery after it has been treated with angioplasty or stenting).

About PVS-10200

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Pervasis' therapies harness the power of the endothelium, the thin layer of cells that lines the interior surface of blood vessels, which has a well-understood role in regulating many of the body's healing processes, including vascular repair. PVS-10200 is a biologically active therapy developed using tissue-engineered allogeneic endothelial cells, and is designed to reestablish healthy vasculature following common interventions to treat PAD and potentially other conditions. PVS-10200 builds on the same proprietary endothelial technology and mechanism of action underlying Vascugel[®], Pervasis' most advanced program, which has demonstrated proof of concept and safety in two Phase 2 trials in patients undergoing vascular access procedures for hemodialysis. In February 2010, the company announced that it received approval of a Special Protocol Assessment from the U.S. Food and Drug Administration to conduct one Phase 3 pivotal trial of Vascugel.

"With limited treatment options for PAD and a high rate of serious complications associated with the options that are available to these patients, there is a significant unmet need for therapies to address the underlying processes leading to common intervention failures," said Frederic Chereau, president and chief executive officer of Pervasis. "The findings presented today add to the growing body of evidence demonstrating the safety and efficacy of our cell-based approach to enabling vascular repair. We look forward to completing the study in the coming months, presenting final data, and continuing to further our development program for this important therapy for patients with PAD and other serious diseases."

About Peripheral Arterial Disease

More than eight million Americans over the age of 50 have peripheral arterial disease (PAD), a serious condition in which plaque builds up in arteries, restricting blood flow. PAD has significant health implications, including high blood pressure, reduced ability to walk, leg pain, and increased risk for heart attack and stroke.

When lifestyle changes and medication are not enough, treatment often involves surgical intervention, such as angioplasty or stent placement. In the U.S., approximately 300,000 peripheral stent or angioplasty procedures occur annually. However, in many cases, the artery does not heal properly following intervention, which can lead to restenosis and cause serious complications, including limb amputation.

About Pervasis

Pervasis Therapeutics, Inc. is a clinical stage company developing a broad portfolio of biologically active therapeutics. Building on its deep understanding of the specialized role that the endothelium plays in regulating natural healing and repair processes associated with disease, Pervasis is advancing groundbreaking new therapies to dramatically improve the outcomes of common vascular interventions, such as arteriovenous access, angioplasties,

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stents, and peripheral and coronary bypass grafts – the failure of which result in serious complications and a significant increase in medical costs. The company's most advanced program, Vascugel[®], has demonstrated proof of concept and safety in two Phase 2 trials in patients undergoing vascular access for hemodialysis. In addition, Pervasis is pursuing a cell-based oncology program focused on targeting and regulating cell stroma in order to prevent key processes that play a role in advancing solid tumor growth and survival. Pervasis is also applying its platform technology to develop products in other key therapeutic areas including inflammatory disease and orthopedic injury.

Pervasis is a privately held company with funding from Flagship Ventures, Polaris Venture Partners, Highland Capital Partners and the Richter Family Fund. For more information, please visit www.pervasistx.com.

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PERVASIS THERAPEUTICS TO DEVELOP NOVEL CELL-BASED APPROACH TO TARGET TUMOR ENVIRONMENT, PREVENT CANCER RECURRENCE

-- Bolstered by Landmark Research and Multiple Preclinical Studies, Groundbreaking Therapy Holds Promise to Deliver Safe, Effective Cell Therapy Treatment for Solid Tumors --

Cambridge, Mass. – January 19, 2011 – Pervasis Therapeutics, Inc. today announced that the company is pursuing a matrix-embedded endothelial cell-based therapy (PVS-30200) to target and regulate cell stroma (the tumor environment or “ecosystem” that is comprised of various supporting cell types distinct from cancer cells) in order to prevent key processes that play a role in advancing solid tumor growth and metastasis (the spread of cancer cells to secondary locations). A cornerstone of Pervasis’ oncology program, the company has entered into an exclusive patent license agreement with the Massachusetts Institute of Technology (MIT) for all discovery and development activities associated with cellular implants for cancer diagnosis, prognosis and treatment. In addition, supportive evidence from multiple preclinical studies demonstrates the powerful anti-angiogenic, anti-proliferative and anti-inflammatory properties of this endothelial cell-based approach in the presence of various solid tumor cancers, such as brain, lung, breast and prostate.

Pervasis, a clinical stage company based in Cambridge, Mass., is focused on developing breakthrough cell-based therapies that harness the healing power of the endothelium, the thin layer of cells that lines the interior surface of every blood vessel in the body. The company’s other areas of clinical investigation include improving outcomes following common vascular surgical and interventional procedures, such as hemodialysis access, angioplasties, stents and peripheral and coronary bypass grafts—the failures of which result in serious complications and a significant increase in medical costs.

“We are very excited to expand our focus to include the critical area of oncology,” stated Frederic Chereau, president and chief executive officer of Pervasis. “We already have amassed a significant amount of data demonstrating the safety and efficacy of utilizing our novel cell-based approach to improve outcomes associated with the treatment of other serious conditions. We look forward to leveraging this body of knowledge to develop a novel therapy that could lead to a safer, more effective treatment for solid tumors, preventing cancer recurrence and improving outcomes for cancer patients.”

The Role of Endothelial Cells in Regulating Cancer Cell Behavior

Endothelial cells are critical to tissue repair and health, and have a well-understood role in regulating many of the body’s healing processes, including those associated with vascular repair. Endothelial cells work as the body’s “police force” – helping maintain homeostasis and control cells under a range of pathologic stresses. The research done at MIT upon which the

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licensed patent portfolio is based was led by Elazer Edelman, MD, PhD, Professor of Health Sciences and Technology at MIT and Professor of Medicine at Harvard Medical School, and Joseph Franses, a graduate student in the MIT Division of Health Sciences and Technology. They demonstrated that endothelial cells are a critical component of the tumor cell stroma and serve a similar role in cancer biology as they do in vascular biology, regulating cancer cell behavior, and suppressing proliferation, invasiveness and inflammation.

There is growing evidence that invasive tumor growth results from communication between cancer cells and the surrounding host cell stroma. To that end, the breakthrough MIT research, which was published today in *Science Translational Medicine*¹⁰, suggests that, in the tumor setting, quiescent endothelial cells are tumor-suppressive and slow the proliferation and invasiveness of cancer cells (as studied in culture and in animals), while disruption of the endothelial cells eliminates their ability to inhibit these actions that cause metastasis. Introducing exogenous functional, healthy endothelial cells to the stromal area can restore homeostasis.

“We are highly encouraged by our initial findings, as we believe they significantly advance our understanding of the critical role endothelial cells play in inhibiting many of the aggressive aspects of cancer,” stated Dr. Edelman, who is one of the original founders of Pervasis and a current member of the company’s Board of Directors. “We believe this research will open the door to vast horizons for future research and the development of novel therapies, and we look forward to the work Pervasis is undertaking to advance these concepts to the clinical stage.”

PVS-30200 – Advantages over Current Cancer Therapies

Many current approaches to treating cancer are plagued by significant limitations such as high toxicity and serious side effects, and are systemic in nature, unable to locally target tumors. In addition, despite addressing the primary tumor, metastasis remains one of the most challenging aspects of treating cancer, and is a process that is often unpreventable and uncontrollable.

PVS-30200 utilizes Pervasis’ proprietary implantable material comprised of healthy allogeneic endothelial cells embedded in a polymer matrix that is delivered locally at the time of tumor excision to prevent cell-proliferation, inflammation and angiogenesis, key processes that lead to tumor growth and survival. The well-studied patented technology on which PVS-30200 is founded has a proven safety profile, as demonstrated by data from six clinical studies, and can be administered and targeted locally at the site of the tumor. A novel cell therapy approach, PVS-30200’s use of allogeneic cells, as opposed to autologous cells, enables “off the shelf”

¹⁰ J. W. Franses, A. B. Baker, V. C. Chitalia, E. R. Edelman, Stromal Endothelial Cells Directly Influence Cancer Progression. *Sci. Transl. Med.* 3, 66ra5 (2011).



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administration, eliminating the challenging logistical processes that are involved with the use of autologous cells.

“We plan to present our preclinical findings as well as the PVS-30200 technology to the oncology community as soon as possible; we believe this therapy has the potential to dramatically advance the promise of cell therapy as an innovative and viable treatment paradigm for cancer,” said Mr. Chereau.

Pervasis’ Current Clinical Programs

Pervasis is currently conducting a Phase 1/2 clinical study of PVS-10200, an investigational new drug under development to prevent restenosis in patients with peripheral arterial disease who undergo angioplasty and stent placement in the superficial femoral artery. The company’s most advanced program, Vascugel®, has demonstrated proof of concept and safety in two Phase 2 trials in patients undergoing arteriovenous access procedures for hemodialysis. In 2010, Pervasis announced that it had reached an agreement with the U.S. Food and Drug Administration (FDA) for its Phase 3 clinical trial of Vascugel under the FDA’s Special Protocol Assessment (SPA) procedure. Through the SPA procedure, FDA formalized its agreement that the design of the Phase 3 trial was acceptable to support a regulatory submission seeking new drug approval.

About Pervasis

Pervasis Therapeutics, Inc. is a clinical stage company developing a broad portfolio of biologically active therapeutics. Building on its deep understanding of the specialized role that the endothelium plays in regulating natural healing and repair processes associated with disease, Pervasis is advancing groundbreaking new therapies to dramatically improve the outcomes of common vascular interventions, such as arteriovenous access, angioplasties, stents, and peripheral and coronary bypass grafts – the failure of which result in serious complications and a significant increase in medical costs. The company’s most advanced program, Vascugel®, has demonstrated proof of concept and safety in two Phase 2 trials in patients undergoing vascular access for hemodialysis. In addition, Pervasis is pursuing a cell-based oncology program focused on targeting and regulating cell stroma in order to prevent key processes that play a role in advancing solid tumor growth and survival. Pervasis is also applying its platform technology to develop products in other key therapeutic areas including inflammatory disease and orthopedic injury.

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**PERVASIS THERAPEUTICS AWARDED FOUR GRANTS UNDER THE QUALIFYING
THERAPEUTIC DISCOVERY PROJECT**

-- Clinical stage company focused on breakthrough therapies to improve outcomes following vascular surgical and interventional procedures --

-- Novel endothelial formulations may be applicable to other therapeutic fields including inflammatory disease, orthopedic injury and cancer --

Cambridge, Mass. – November 5, 2010 – Pervasis Therapeutics, Inc. today announced that it has been awarded over \$920,000 in grants through the U.S. government's Qualifying Therapeutic Discovery Project, which provides tax credits and grants to projects that show significant potential to produce new therapies, reduce long-term health care costs, or significantly advance the goal of curing cancer within the next 30 years.

Pervasis is a clinical stage company focused on developing breakthrough therapies with the potential to improve outcomes following common vascular surgical and interventional procedures, such as arteriovenous access, angioplasties, stents and peripheral and coronary bypass grafts—the failure of which result in serious complications and a significant increase in medical costs. There are no currently approved therapies that directly target the underlying physiological processes leading to serious vascular complications, including inflammation, thrombosis (the formation of a blood clot inside a blood vessel) and restenosis (the re-narrowing of a coronary artery after it has been treated with angioplasty or stenting).

Pervasis' therapies harness the power of the endothelium, the thin layer of cells that lines the interior surface of blood vessels, which has a well-understood role in regulating many of the body's healing processes, including vascular repair. Because these endothelial formulations secrete several key factors involved in combating inflammation and restenosis, they may also be applicable to other therapeutic fields where surgical or interventional procedures are required, including inflammatory disease, orthopedic injury and cancer.

The grants awarded to Pervasis span several therapeutic fields for which the company's therapies have application including:

- Development of PVS-10200 for Peripheral Artery Disease (\$244,479.25)
- Development of Vascugel® to Sustain Arteriovenous Access for Hemodialysis (\$244,479.25)
- Development of Tissue-Engineered Endothelial Cell Therapy to Supplement Orthopedic Procedures (\$244,479.25)
- Development of Tissue-Engineered Endothelial Cell Therapy for Brain and Prostate Cancer (\$191,420.94)

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“The awarding of these grants validates our belief that our breakthrough therapies offer fundamentally new approaches to improving outcomes for vascular surgical and interventional procedures, as well as the potential to address unmet needs associated with several other critical disease areas, such as cancer,” said Frederic Chereau, president and chief executive officer of Pervasis. “We look forward to continuing our research and development of these important therapies in order to bring them to patients as quickly as possible.”

A Phase I/II study is currently underway in France to evaluate PVS-10200, an investigational new drug under development by Pervasis to prevent restenosis in patients with peripheral arterial disease who undergo an angioplasty and stent procedure in the superficial femoral artery. The company’s most advanced program, Vascugel®, has demonstrated proof of concept and safety in two Phase 2 trials in patients undergoing arteriovenous access procedures for hemodialysis. Earlier this year, Pervasis announced that it had reached an agreement with the U.S. Food and Drug Administration (FDA) for its Phase 3 clinical trial of Vascugel under the FDA’s Special Protocol Assessment (SPA) procedure. Through the SPA procedure, FDA formalized its agreement that the design of the Phase 3 trial was acceptable to support a regulatory submission seeking new drug approval.

The Qualifying Therapeutic Discovery Project, established under section 48D of the Internal Revenue Code, is a \$1 billion fund, available to firms with no more than 250 employees. The credit or grant covers up to 50 percent of the cost of qualifying biomedical research.

About Pervasis

Pervasis Therapeutics, Inc. is a clinical stage company developing a broad portfolio of biologically active therapeutics. Building on its deep understanding of the specialized role that endothelium plays in regulating natural healing and repair processes associated with disease, Pervasis is advancing groundbreaking new therapies to dramatically improve the outcomes of common vascular interventions, such as arteriovenous access, angioplasties, stents, and peripheral and coronary bypass grafts – the failure of which result in serious complications and a significant increase in medical costs. The company’s most advanced program, Vascugel®, has demonstrated proof of concept and safety in two Phase 2 trials in patients undergoing arteriovenous access procedures for hemodialysis. Pervasis is also applying its platform technology to develop products in therapeutic areas beyond vascular disease, including inflammatory disease, orthopedic injury and cancer.

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**FREDERIC CHEREAU, PRESIDENT AND CEO OF PERVASIS THERAPEUTICS HONORED
AS A RECIPIENT OF MASS HIGH TECH'S 2010 ALL-STARS AWARDS**

— Clinical stage company developing novel therapeutics to promote vascular repair, improve outcomes following common surgical and interventional procedures —

Cambridge, Mass. – October 28, 2010 – Pervasis Therapeutics, Inc. today announced that Frederic Chereau, president and chief executive officer of the company, is among the recipients of Mass High Tech's 2010 All-Stars Awards, which recognize 16 dynamic and influential leaders of New England's innovation economy.

Pervasis is a clinical stage company focused on developing breakthrough therapies with the potential to improve outcomes following common vascular surgical and interventional procedures, such as arteriovenous access, angioplasties, stents and peripheral and coronary bypass grafts—the failure of which result in serious complications and a significant increase in medical costs. There are no currently approved therapies that directly target the underlying physiological processes leading to serious vascular complications, including inflammation, thrombosis (the formation of a blood clot inside a blood vessel) and restenosis (the re-narrowing of a coronary artery after it has been treated with angioplasty or stenting).

“I am honored to be selected as a recipient of this award, particularly in the company of such notable leaders in the high tech and life sciences industries,” said Mr. Chereau. “At Pervasis, we are proud to be a part of this region's continued excellence in innovation. We strongly believe that our product candidates offer fundamentally new approaches to treating vascular diseases which impact millions of people. We look forward to continuing to research these important therapies for vascular disease and other therapeutic areas, and to contributing to New England's rich life sciences heritage.”

Pervasis' therapies harness the power of the endothelium, the thin layer of cells that lines the interior surface of blood vessels, which has a well-understood role in regulating many of the body's healing processes, including vascular repair. The company's lead development programs are focused on two areas of intense need: improving arteriovenous access procedures for hemodialysis patients, and reducing the longer-term problems that limit the success of angioplasty or stent implants for patient with peripheral arterial disease (PAD), a serious condition affecting more than eight million Americans over the age of 50.

A Phase I/II study is currently underway in France to evaluate PVS-10200, an investigational new drug under development by Pervasis to prevent restenosis in patients with PAD who undergo an angioplasty and stent procedure in the superficial femoral artery. The company's

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most advanced program, Vascugel®, has demonstrated proof of concept and safety in two Phase 2 trials in patients undergoing arteriovenous access procedures for hemodialysis.

Mr. Chereau has been president and chief executive officer at Pervasis since September 2008. Prior to Pervasis, Mr. Chereau was the Vice President and General Manager of Genzyme Cardiovascular, a business unit of Genzyme Corporation. In addition, Mr. Chereau served as chief operating officer of MG Biotherapeutics LLC, a Genzyme and Medtronic joint-venture formed to develop cellular therapies for cardiac repair. In addition to Pervasis, Mr. Chereau also serves as a member of the board of directors of the French-American Chamber of Commerce New England Chapter (FACCNE).

The 2010 Mass High Tech All-Stars honorees represent a broad range of technology and service sectors, including robotics, mobile technology, hardware, health care, Internet and biotech. They were selected from more than 200 nominees recommended by the technology community. Mr. Chereau and the other honorees are profiled in a special edition of Mass High Tech that was issued yesterday, and will be recognized at an awards celebration this evening at the Intercontinental Hotel in Boston. More information about the event is available at <http://masshightech.bizjournals.com/masshightech/event/26971>.

About Pervasis

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PERVASIS PROVIDES UPDATE ON PROGRESS OF CLINICAL PROGRAM

TARGETING PERIPHERAL ARTERIAL DISEASE

— First Cohort of Patients Enrolled in Phase 1/2 Trial to Evaluate PVS-10200 in Prevention of Restenosis Following Stent and Angioplasty Procedure in Superficial Femoral Artery —

Cambridge, Mass., June 22, 2010 — Pervasis Therapeutics announced today that the first cohort of patients has been fully enrolled in the Phase 1/2 clinical study of PVS-10200, an investigational new drug under development to prevent restenosis in patients with peripheral arterial disease (PAD) who undergo an angioplasty and stent procedure in the superficial femoral artery. Initial study results from this patient cohort are expected at the end of 2010.

"PAD is now being recognized as a national public health threat, as evidenced by the recent introduction of the U.S. Congressional PAD Resolution to improve diagnosis and care," said Fred Chereau, chief executive officer, Pervasis Therapeutics. "Currently available treatment options for PAD are limited, and the rate of restenosis following stent and angioplasty procedure is high. Based on preclinical data for PVS-10200 and positive clinical results from our lead product, Vascugel[®], we believe PVS-10200 has the potential to improve outcomes for patients with PAD."

"The Phase 1/2 study of PVS-10200 will help evaluate this therapy as an adjunct to an angioplasty and stent procedure in real-world practice," stated Dr. Jean-Marc Alsac of Hôpital Européen Georges Pompidou, Paris. "New therapies that could help re-establish healthy vasculature, such as PVS-10200, would provide a valuable treatment option for physicians and patients. PVS-10200 is quickly and easily administered through a minimally invasive procedure and does not extend hospitalization time for patients."

The open-label dose escalation trial will evaluate the safety and impact of PVS-10200 on the incidence of major adverse events. Secondary endpoints will include the rate of primary patency and restenosis, and the time to re-intervention. The first cohort includes 11 patients. Approximately 20 patients are expected to enroll in the second cohort and will receive a higher dose of PVS-10200.

The study is being conducted at three medical centers in France and is led by Dr. Jean-Marc Alsac at Hôpital Européen Georges Pompidou, Dr. Yves Castier at Hôpital Bichat, Paris, and Dr. Marie-Antoinette Sevestre at Centre Hospitalier Universitaire d'Amiens.

PVS-10200 is a biologically active therapy developed using tissue-engineered allogeneic endothelium, and is designed to reestablish healthy vasculature following common interventions to treat PAD and potentially other conditions. PVS-10200 builds on the same proprietary endothelial technology and mechanism of action underlying Vascugel[®], Pervasis' investigational ***Copyright 2011 Pervasis Therapeutics, Inc.***



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new drug for the prevention of hemodialysis access graft failure. In February 2010, the company announced that it received approval of a Special Protocol Assessment from the U.S. Food and Drug Administration to conduct one Phase 3 pivotal trial of Vascugel®.

About Peripheral Arterial Disease

More than eight million Americans over the age of 50 have peripheral arterial disease (PAD), a serious condition in which plaque builds up in arteries, restricting blood flow. PAD has significant health implications, including high blood pressure, reduced ability to walk, leg pain, and increased risk for heart attack and stroke.

When lifestyle changes and medication are not enough, treatment often involves surgical intervention, such as angioplasty or stent placement. In the U.S., approximately 300,000 peripheral stent or angioplasty procedures occur annually. However, in many cases, the artery does not heal properly following intervention, which can lead to restenosis and cause serious complications, including limb amputation.

About Pervasis

Pervasis Therapeutics, Inc. is a clinical stage company developing a broad portfolio of biologically active therapeutics. Building on its deep understanding of the specialized role that the endothelium plays in regulating natural healing and repair processes associated with disease, Pervasis is advancing groundbreaking new therapies to dramatically improve the outcomes of common vascular interventions, such as arteriovenous access, angioplasties, stents, and peripheral and coronary bypass grafts – the failure of which result in serious complications and a significant increase in medical costs. The company's most advanced program, Vascugel®, has demonstrated proof of concept and safety in two Phase 2 trials in patients undergoing arteriovenous access procedures for hemodialysis. Pervasis is also applying its platform technology to develop products in therapeutic areas beyond vascular disease, such as inflammatory, oncology and orthopedic diseases.

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**PERVASIS ANNOUNCES START OF SECOND CLINICAL PROGRAM,
TARGETING PERIPHERAL ARTERIAL DISEASE**

*— Phase 1/2 Trial to Evaluate PVS-10200 in Prevention of Restenosis Following
Stent and Angioplasty Procedure —*

Cambridge, Mass., April 7, 2010 – Pervasis Therapeutics announced today that it enrolled the first patient in a new Phase 1/2 clinical study exploring the potential of PVS-10200 to prevent restenosis in patients who undergo an angioplasty and stent procedure for the treatment of peripheral arterial disease (PAD).

The open-label dose escalation trial will enroll patients at three medical centers in France. Primary endpoints include safety and the impact of PVS-10200 on the incidence of major adverse events. Secondary endpoints include the rate of primary patency and restenosis, and the time to re-intervention. Initial results are expected in the second half of 2010.

“We are tremendously excited to advance our second major pipeline program into clinical testing, targeting a critical need for patients affected by PAD,” said Fred Chereau, chief executive officer, Pervasis Therapeutics. “Peripheral arterial disease remains a poorly controlled condition, leading to an estimated 75,000 limb amputations each year in the United States. Based on the positive clinical results of our lead product Vascugel[®], combined with our compelling PAD preclinical results, we are encouraged that PVS-10200 may play an important role in improving the care of PAD, either as an adjunct to stents and catheters or as a stand-alone therapy.”

The Phase 1/2 trial for PVS-10200 is ongoing in France, led by Dr. Jean-Marc Alsac at Hôpital Européen Georges Pompidou, Dr. Yves Castier at Hôpital Bichat, and Dr. Marie-Antoinette Sevestre at Centre Hospitalier Universitaire d’Amiens.

PVS-10200 is a biologically active therapy developed using tissue-engineered allogeneic endothelium, and is designed to reestablish healthy vasculature following common interventions to treat PAD and potentially other conditions. Preclinical results for PVS-10200 published in the December 2009 *Journal of Vascular and Interventional Radiology* (Nugent et al. *J Vasc Interv Radiol* 2009; 20(12):1617-1624) demonstrated that administration at the time of angioplasty and stent placement enhanced blood vessel healing compared to angioplasty and stents alone in a porcine model.

PVS-10200 builds on the same proprietary endothelial technology and mechanism of action underlying Vascugel[®], Pervasis’ investigational new drug for the prevention of hemodialysis access graft failure. In February 2010, the company announced that it received approval of a Special Protocol Assessment from the U.S. Food and Drug Administration to conduct one Phase 3 pivotal trial of Vascugel[®].

About Peripheral Arterial Disease

More than eight million Americans over the age of 50 have peripheral arterial disease (PAD), a serious condition in which plaque builds up in arteries, causing the restriction of blood flow. PAD has significant

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health implications, including high blood pressure, reduced ability to walk, and increased risk for heart attack and stroke.

When lifestyle changes and medication are not enough, treatment often involves surgical intervention, such as angioplasty or stent placement. In the U.S., approximately 300,000 peripheral stent or angioplasty procedures occur annually. However, in many cases, the artery does not heal properly following intervention, which can lead to restenosis and cause serious complications, including limb amputation.

About Pervasis

Pervasis Therapeutics, Inc. is a clinical stage company developing a broad portfolio of biologically active therapeutics. Building on its deep understanding of the specialized role that the endothelium plays in regulating natural healing and repair processes associated with disease, Pervasis is advancing groundbreaking new therapies to dramatically improve the outcomes of common vascular interventions, such as arteriovenous access, angioplasties, stents, and peripheral and coronary bypass grafts – the failure of which result in serious complications and a significant increase in medical costs. The company's most advanced program, Vascugel[®], has demonstrated proof of concept and safety in two Phase 2 trials in patients undergoing arteriovenous access procedures for hemodialysis. Pervasis is also applying its platform technology to develop products in therapeutic areas beyond vascular disease, such as inflammatory, oncology and orthopedic diseases.

Pervasis is a privately held company with funding from Flagship Ventures, Polaris Venture Partners, Highland Capital Partners and the Richter Family Fund. For more information, please visit www.pervasistx.com.

This news release contains certain forward-looking statements that involve risks and uncertainties. Such statements are only predictions and the company's actual results may differ materially from those anticipated in these forward-looking statements. Factors that may cause such differences include the timing of clinical trials, the risk that products that appeared promising in early research and clinical trials do not demonstrate safety or efficacy in clinical trials and the risk that the company will not obtain approval to market its products.



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**PERVASIS THERAPEUTICS RECEIVES FDA CLEARANCE
FOR PIVOTAL PHASE 3 TRIAL OF VASCUGEL®**

— Agreement Follows Recent Publication of Data for Lead Programs in ESRD, PAD —

Cambridge, Mass. – February 1, 2010 – Pervasis Therapeutics, Inc. today announced that it has reached an agreement with the U.S. Food and Drug Administration (FDA) on the design of a pivotal Phase 3 clinical trial for Vascugel®, an investigational new drug for the prevention of hemodialysis access graft failure. The agreement was made under the FDA's Special Protocol Assessment (SPA) procedure. Pervasis expects to initiate the study in 2010.

"We are pleased that the FDA approved the SPA agreement and are confident that we now have a clearly defined path to submission of a Biologics License Application for Vascugel," said Fred Chereau, president and chief executive officer at Pervasis. "We look forward to beginning the Phase 3 study and to confirming the safety and efficacy results from our Phase 1/2 study in a larger patient population."

This Phase 3, single-blind, randomized, controlled, multi-center study will evaluate the efficacy and safety of Vascugel in approximately 390 patients with end-stage renal disease (ESRD) undergoing creation of an arteriovenous (AV) graft for hemodialysis access. The primary objective of this study will be to evaluate the efficacy of Vascugel in extending the duration of primary patency (lack of vessel obstruction) as compared to standard-of-care treatment.

Under the SPA procedure, FDA formalizes its agreement that the design of the Phase 3 trial is acceptable to support a regulatory submission seeking new drug approval.

The SPA agreement follows the recent publication of positive Phase 1/2 results for Vascugel in the December issue of the *Journal of Vascular Surgery* (Conte et al. *J Vasc Surg* 2009; 50:1359-68). The study was designed to assess feasibility, safety, and preliminary effects on patency of Vascugel in patients requiring an AV fistula or AV graft for hemodialysis. Results showed that Vascugel was well tolerated, with no difference in early complication rates between the Vascugel and placebo groups at four weeks (10.9 percent vs. 21.1 percent, respectively). Results also demonstrated a trend for improved primary patency at 24 weeks in patients treated with Vascugel compared to placebo.

Building on the successful results to date for Vascugel, Pervasis continues to apply its proprietary endothelial technology platform to develop additional therapies to treat vascular disease. Data for PVS-10200, a preclinical compound being developed to treat interventions performed for peripheral arterial disease (PAD), were published in the December issue of the *Journal of Vascular and Interventional Radiology* (Nugent et al. *J Vasc Interv Radiol* 2009; 20(12):1617-1624). In a preclinical model of PAD, administration of PVS-10200 at the time of angioplasty and stent placement enhanced blood vessel healing compared to angioplasty and stenting alone. Pervasis is now preparing to begin a Phase 1/2 study of PVS-10200 in the first half of 2010.

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Pervasis Therapeutics, Inc. is a clinical stage company developing a broad portfolio of biologically active therapeutics. Building on its deep understanding of the specialized role that the endothelium plays in regulating natural healing and repair processes associated with disease, Pervasis is advancing groundbreaking new therapies to dramatically improve the outcomes of common vascular interventions, such as arteriovenous access, angioplasties, stents, and peripheral and coronary bypass grafts – the failure of which result in serious complications and a significant increase in medical costs. The company's most advanced program, Vascugel[®], has demonstrated proof of concept and safety in two Phase 2 trials in patients undergoing arteriovenous access procedures for hemodialysis. Pervasis is also applying its platform technology to develop products in therapeutic areas beyond vascular disease, such as inflammatory and orthopedic diseases.

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About Vascugel and PVS-10200

Vascugel, a novel, biologically active therapy developed using tissue-engineered allogeneic endothelium, is under investigation for enhancing blood vessel repair and promoting vascular health. In May 2009, Vascugel received an Orphan Drug designation from the U.S. Food and Drug Administration for the prevention of arteriovenous fistula or arteriovenous graft failure in patients with end-stage renal disease.

PVS-10200, a biologically active therapy developed using tissue-engineered allogeneic endothelium, is designed to reestablish healthy vasculature following common interventions to treat peripheral arterial disease (PAD) and potentially other conditions. PAD is a systemic disease in which plaque builds up in arteries, causing the restriction of blood flow that can lead to serious complications, including limb amputation, kidney failure, stroke and death.

About end-stage renal disease (ESRD)

End-stage renal disease (ESRD) is an advanced and irreversible condition treated mainly by hemodialysis or kidney transplantation. It is estimated more than 350,000 Americans with ESRD receive hemodialysis each year.ⁱ Complications following AV access procedures for hemodialysis are common, and an estimated 60 percent of AV grafts fail after one year.^{ii,iii} Vascugel may represent a fundamentally new approach to preventing AV access failure by helping to regulate the body's healing response following the creation of an AV access site.

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ⁱ <http://kidney.niddk.nih.gov/kudiseases/pubs/kustats/index.htm>. Last accessed January 27, 2010.

ⁱⁱ Dixon et al. DAC Study Group. Effect of dipyridamole plus aspirin on hemodialysis graft patency. *N Engl J Med.* 2009; 360: 2191-2201.

ⁱⁱⁱ Hayashi et al. Vascular access for hemodialysis. *Nat Clin Pract Nephrol.* 2006; 2: 504-513.

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