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Change, Innovation and Investment in the "New Healthcare Economy"

2009 OUTLOOK ON HEALTHCARE VENTURE CAPITAL
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EDITOR'S NOTE: This paper is the first "annual outlook" published by healthcare venture capital firm Psilos Group. Psilos has been investing in the healthcare economy since 1998, and the firm's partners have more than 135 years combined experience in healthcare venture investing and healthcare company management and consulting. The outlook is intended to provide investors, analysts, businesses and policy-makers with a guide to the issues and trends that will shape healthcare growth investing in 2009 and beyond.

Healthcare investing will not be for the faint of heart in 2009. The combined impact of a tough economy, spiraling healthcare costs and a new U.S. presidential administration will result in significant uncertainty and risk for investors.

At the same time, the "change" that swept President Obama into office will have to find its way into the hospitals, clinics, labs, doctor's offices and insurance providers that make up the U.S. healthcare system if America is to remain competitive. The rate of healthcare inflation – which is currently twice the core inflation rate – can clearly no longer be supported, and changes are required to address the explosion in America's aging population over the next two decades. Experts estimate that roughly one third of all medical care delivered in the United States is wasted or in error, suggesting there is ample room for improvement.

In spite of the bleak near-term indicators, we predict that the United States is poised to establish a "new healthcare economy." Starting in 2009, we expect to see a ten-year transformational cycle that will re-define many dynamics of the American healthcare system. The new healthcare economy will depend on innovation to simultaneously drive down costs and improve quality of care – core criteria cited by President Obama in his inaugural address. It will also require better alignment of economic incentives across payers, providers and patients.

As long-term healthcare investors, we are optimistic about the incredible opportunities and growth ahead in the new healthcare economy. At the same time, we can't ignore the shocking contrast in priorities between President Obama's healthcare plans, which call for billions of dollars in funding to improve healthcare IT and services, and the venture industry's traditional investment focus. According to 2008 data released by the National Venture Capital Association, just $195 million of the $28.3 billion invested by venture firms in 2008 went to healthcare services – less than one percent. Similarly, Dow Jones VentureSource shows only $354 million invested in healthcare IT and $357 million for healthcare services in 2008, accounting for less than three percent of all venture investing. Unfortunately, this lack of investment in a critical area of our economy is not a new phenomenon.

Using NVCA data, healthcare services funding ($195 million) was dwarfed by software ($4.9 billion), industrial/energy ($4.6 billion), biotech ($4.5 billion), medical devices ($3.4 billion), and digital media and entertainment ($2.0 billion). In fact, NVCA data shows healthcare services in 2008 had fewer deals and dollars invested than any of the past 10 years, and VentureSource shows declining funds for healthcare IT for the last six years. Even medical devices, which posted strong growth from 2003 ($1.67 billion) to 2007 ($4.07 billion) according to NVCA, fell by 15% in 2008 with a steep dropoff in Q4.

To address this "innovation gap," we urge the venture industry to step up "health tech" funding similar to the way it has stepped up "clean tech" funding, which grew 52% in 2008 to reach $4.1 billion. Specifically, we challenge the industry to expand its annual investment rates to more than $1 billion in healthcare services, $1 billion in healthcare IT, and $3.6 billion in medical technologies (including both medical devices and diagnostics).

Combined, those "health tech" levels would represent 20% of the current annual venture funding rate, well above today's 13% to 14% (which includes medical devices, healthcare IT and healthcare services, but not biotechnology which we include with pharmaceuticals as a separate category of "life sciences"). Since healthcare currently represents 16.2% of U.S. GDP and is expected to grow to 19.5% of GDP by 2017, this increased venture investment would help over-correct the current shortfall and give the new healthcare economy a needed "booster shot" of innovation.

This venture-driven investment will be critical to spur development of the new healthcare economy. As with most mature industries, innovation will be driven by smaller companies and private ventures, which can afford to make riskier long-term investments, while larger healthcare providers and payers focus primarily on preserving market share and navigating reforms. Longer term, Psilos predicts those innovations will be adopted by mainstream providers and payers as the only way to achieve the dual but consistent goals of cost reductions and quality improvements.

The bottom line: This is an exciting time for growth investors in the new healthcare economy, which should reward young companies that apply methods of achieving value and efficiency, as has been succesful in other industries. We hope the venture industry sees President Obama's plans as a wake-up call to get serious about the economics of healthcare, not just the science of biotech. The risk and reward dynamics of this new environment are tailor-made for venture capital, and our nation needs us as a partner in this important venture.

The Case for Healthcare Innovation & Investment

Psilos believes that venture investment opportunities in the healthcare economy over the next ten years and beyond will be driven by an imperative to create and deploy business and technological solutions to the ongoing U.S. healthcare crisis. Current estimates put U.S healthcare spending at approximately 16.2% of Gross Domestic Product ('GDP") and it is expected to grow to 19.5% of GDP by 2017, indicating that the growth in healthcare expenditures will continue to significantly outpace the growth in overall GDP. This trajectory in healthcare spending has already had a negative impact on the global competitiveness of U.S. based corporations. Analysts and economists forecast that, if left unchecked, the current trend will likely bankrupt Medicare and Medicaid within the near future.

Yet, at the same time, political momentum continues to build towards some form of mandated universal healthcare coverage for all Americans. Under these circumstances there is enormous pressure on the healthcare system to innovate in the direction of enhancing the quality of care and reducing overall costs. This is a particularly acute need in light of the rapid aging of the American population and the ever-expanding cost of treating chronic disease.

Psilos believes that the innovation necessary to address the challenges in the healthcare system will be driven by private venture-backed companies, who have long been at the forefront in fueling the next generation of ideas. Furthermore, new solutions will require a focus on productivity and value for the healthcare dollar, both of which have long been overlooked in the healthcare industry. We believe this refined focus provides a significant opportunity for venture capital investors to earn substantial equity-based returns by investing in the healthcare economy.

The Current State of the Healthcare Economy

No other sector in the U.S. economy offers the combination of growth, stability and value that is presented by healthcare. The industry is one of the largest segments of the U.S. economy, with total spending of $2.2 trillion in 2007; this figure is expected to nearly double to $4 trillion by 2015, according to the National Coalition on Healthcare. In 2008, while the overall U.S. economy lost over 2 million jobs, the healthcare sector added 500,000 – the only sector to experience significant growth, according to the Bureau of Labor Statistics. In fact, the healthcare sector has, over the past several years, grown significantly faster than the core inflation rate and now represents 16.2% of GDP – and this figure is expected to rise to 19.5% of GDP by 2017 if left unchecked.

Healthcare spending has historically been immune to periods of market downturn, and indeed continues to grow despite what is happening in the greater economy. People continue to get sick regardless of market conditions, and the prevalence of chronic disease is growing. Further, the population is aging at an accelerating rate. More than 10,000 people will age into Medicare every single day for the next 10 years, according to the U.S. Census Bureau. Approximately 38.7 million people are age 65 or older today, but more than 88.5 million people will be age 65 or older by 2050, more than doubling the current figure.

The rapid aging of America will lead to major increases in incidences of expensive chronic illnesses, which already affect more than half of all Americans and account for 70% of all deaths in the U.S. and 75% of the nation's medical care costs, according to the U.S. Center for Disease Control. A recent study by the Milken Institute found that if current chronic disease trends continue, the nation will be spending an additional $1.1 trillion annually by 2023, (representing $217 billion in additional treatment costs and a whopping $900 million in reduced productivity and economic growth); yet the majority of these chronic diseases are manageable or entirely preventable, thus providing a tremendous opportunity to improve clinical quality at a lower cost burden to the nation.

It is generally understood that the current cost trends in healthcare spending will shortly bankrupt Medicare and Medicaid if not addressed, affecting the healthcare of more than 80 million people insured through those programs. For example, in the last 20 years, healthcare programs' share of the Federal budget has doubled, reaching 26% of total spending in 2007 ($717 Billion). According to the PGP Foundation, Medicare's dedicated income from all sources, including general revenues, will not come close to meeting its expenses and by 2040, actuarial projections imply that general revenues will have to provide over 67% of Medicare's financing, up from 40% today, to meet the program's promises. When the Medicare receipts ultimately and inevitably fall short of expenditures, the Treasury will have to find a way to pay the price, either through reduced benefits, higher taxes or increased borrowing.

Furthermore, due to the pressures of unchecked spending, healthcare has negatively impacted the competitiveness of U.S. corporations and it is only getting worse. In fact, the U.S spends a greater percentage of its gross domestic product on healthcare than any other country by almost a factor of two, but it ranks only 25th in global life expectancy. The financial and clinical incentives of payers, providers and patients have become fundamentally misaligned, resulting in poor health habits, medical errors, proliferation of unnecessary or ineffective procedures and pharmaceuticals, and ever-rising costs.

Currently, over 45 million Americans are uninsured according to the Kaiser Family Foundation, and this does not take into account the many millions who are considered "underinsured". A 2008 study reported in Health Affairs found that U.S. patients were at a particularly high risk of forgoing necessary medical treatment because of costs and of experiencing inefficient, poorly organized care or medical errors. As a result, the current healthcare system is characterized by declining public health, decreased corporate sponsorship of healthcare, failed insurance models, the introduction and adoption of expensive clinical interventions (pharmaceutical and otherwise) that do not contribute to improved health, an exodus of physicians from medicine and alarming increases in the role of government in managing the system.

The New Healthcare Economy: A Large-Scale Opportunity for Venture Capital Returns

It is clear that the healthcare economy is a market poised for transformation. As the federal budget deficit and further economic pressures in other sectors of the economy place even greater pressure on the need to address the rising cost of healthcare in America, the market is especially ripe for new business models and innovative solutions to reduce the cost of delivering healthcare across our citizenry while improving the quality of care available across the board. Now, more than ever, there is a rising demand for new business solutions that deliver real <u>value</u> for each healthcare dollar spent by the federal and state governments, U.S. corporations and individual healthcare consumers.

Addressing this crisis requires a multi-pronged approach – prevention, better organization and management of care, and continued medical innovation to better prevent and cure illness. For these reasons, we believe venture capital investors who focus on the healthcare sector are particularly well-positioned to prosper during these difficult economic times.

A major opportunity exists to earn substantial equity-based returns through investment in new, innovative healthcare businesses that rise to the challenge of addressing the value imperative, bringing accountability, efficiency, reduced cost and higher quality to the delivery of healthcare products and services to an expanding and aging population.

Another huge opportunity comes from the application of information technology to realize productivity, quality and other value-enhancing results that have barely begun to penetrate the healthcare sector. As compared to financial services, manufacturing, and transportation, the healthcare industry is massively underinvested in data and technology-driven solutions to enhance the value of services received. However, healthcare industry leaders have recognized this gap and have begun to invest in earnest in the adoption of new technologies to enhance quality of clinical outcome and the opportunity to increase revenue and margin in order to find more economical and effective ways of meeting the growing market demand.

The new Obama administration has clearly signaled their intent to support this trend by discussing a plan for legislation that will commit billions of dollars to spur the adoption of healthcare information technology. At the same time, the federal government, through CMS, has spurred new demand for clinical quality improvement through the adoption of policies that eliminate the reimbursement of hospitals for services (so-called "never events") that result in medical errors, among other actions.

Healthcare Services: The Opportunity

As one of the world's wealthiest nations, the Unites States spends far more on healthcare as a percentage of per capita GDP than other nations and, as previously noted, that expenditure is growing more rapidly than employee wages and virtually every other economic indicator and yet our healthcare system is ranked far from the top of the list in terms of quality and value. It is also worth noting that in past recessions, when the economy has contracted, health spending continued to rise. Most experts predict a continuation of this trend in the current financial climate.

As a result, healthcare reform is considered to be one of the most important issues we face as a country. A recent McKinsey study shows that of the nearly $650 billion we are overspending on healthcare (relative to nations of comparable wealth), the largest amount ($476 billion) comes from excess inpatient and outpatient care expense.

Psilos' investments in the healthcare services sector are focused on businesses that directly lower the cost of care for payers while improving the quality of care on both a population and individual basis. For instance, Psilos was the first institutional investor in Definity Health, the nation's first consumer-driven health plan. Definity delivered to the industry a completely new model for the provision and financing of health benefit plans, combining for the first time consumer education and financial accountability programs with health savings accounts (HSAs) and health reimbursement accounts (HRAs). The company, which was acquired by United Healthcare for over $300 million in 2004, enabled employers to lower their annual health benefit expenditure trend line and achieve significant savings in key areas, such as pharmaceutical costs, where consumers were economically incented to pursue lower cost alternatives, such as generic drugs.

Triveris, our most recent health services investment, further illustrates our approach to identifying transformational models of health services delivery. Triveris is developing "value-based" health plans which integrate personalized health plan design and administration with disease management and prevention as a way to promote healthier members while lowering overall costs for payers. For example, a diabetic who subscribes to such a value-based plan will be financially incented through enhanced benefits and lower out of pocket costs to stay in compliance with their prescribed treatment regimen. This extra cost borne by the payer is relatively minor compared to hospitalizations and other unnecessary costs that arise from complications and co-morbidities of this chronic disease (e.g., amputations, congestive heart failure, blindness, etc.), if left unmanaged.

It is still unknown precisely what form healthcare reform will take in the Obama administration. The crisis we face begs for bold action, yet budget realities brought on by the present economic crisis suggest that incremental reform is more likely in the near term. Though there will be much debate as to the details, we believe there is a general consensus that successful reform must include better disease prevention and chronic care management that engages both patients and their doctors to evidence-based medicine. Additionally, new models of health insurance must be developed to address the uninsured and underinsured challenge, as well as the lack of efficiency of the existing insurance models.

Healthcare IT – The Opportunity

Experts estimate that somewhere between one-third and one-half of total healthcare spending is the result of treatment that is wasteful, redundant or in error. A significant portion of this excess spending relates to administrative and clinical inefficiencies that are a result of antiquated and disparate legacy information technology systems that help run our health insurers, physician offices and hospitals.

There is probably no other industry in the U.S. that is so dramatically underinvested in information technology ("IT") to the detriment of service quality and efficiency. One can look at the transformation of the financial services industry over the past 20 years, which was brought on by a massive investment in systems infrastructure, to see that the healthcare industry remains in the dark ages by comparison. For example, the credit card industry has seen the creation of third-party merchant processors that enable both outgoing requests for payment and settlement activity – roles that are still divided in the healthcare system. Despite a more than $2 trillion healthcare sector, the federal government (which pays for more than half of those healthcare dollars) spends less than $1 for every $1,000 of national health spending on health systems research.

The failure of IT in healthcare in terms of standardization and interoperability has important repercussions beyond streamlining administrative inefficiencies, which alone account for an estimated $90 billion of excess healthcare expenditures annually. The current state of hospital and physician practice management systems leads to poor information about the management of patients' care which results in overall higher cost and lower quality of healthcare in the United States. Hundreds of thousands of hospital deaths each year are a result of avoidable medical errors that could have been prevented by better, timelier medical information. Without robust systems and shared information, providers lack the clinical decision-support and care coordination tools that can dramatically improve the quality of care that is delivered based on the latest research and evidence based medicine, and without intelligent healthcare data collection and dissemination (i.e., a personal electronic health record), all but the most diligent patients are completely disconnected from the management of their own care.

Furthermore, in an industry that has usually been quick to adopt new technologies for treatment, the adoption of healthcare IT (such as electronic medical records, computerized physician order entry systems, and computerized decision support systems) has been very slow. True adoption of widespread effective IT for maximum national gain requires a transformative approach that spans ambulatory, diagnostic, pharmacy and inpatients settings.

The relationship between inadequate IT systems and a poor cost/quality dynamic is well understood by healthcare experts, and it is evident that a major investment in IT infrastructure will be central to reform efforts aimed at improving the healthcare system (and perhaps to overall economic stimulus as well). Hospitals have just begun to make the investment in upgraded IT solutions in order to address administrative inefficiency vis-à-vis payers, and improved quality of care for their patients. Insurance carriers are also just beginning to make the investment in next generation technologies that enable new models of health insurance to evolve to meet market demands.

Psilos has been a pioneer in the financing and development of healthcare IT companies that meet the needs of the evolving healthcare economy. We financed the first company to establish a meaningful approach to the delivery of clinically-oriented personal health records (Active Health Management), the first company to introduce a fully automated value-based health plan system

(HealthEdge) and benefit plan (Triveris). Key to this success is the identification of IT solutions that not only improve administrative functions but also meaningfully improve the delivery of treatment itself.

One of Psilos' portfolio companies, IntelliDOT, is front and center in this discussion. IntelliDOT is a leading provider or wireless, handheld barcode point-of-care solutions that connect to hospital information systems to improve patient safety and nurse workflow. The IntelliDOT system manages all tasks associated with the 'five rights' medication administration safety checks (i.e., right patient, right time/frequency of administration, right dose, right route of administration and right drug). Already implemented in 55 hospitals, IntelliDOT systems have been shown to enhance patient safety through reducing medication and related errors (where one in five medication administrations are routinely in error), increasing quality of care and improving the hospital's bottom line. Hospitals using IntelliDOT's system have performed over 20 million error-free medication administrations.

Medical Technology – the Opportunity

The medical technology sector has been one of the fastest growing sectors over the last ten years, driven by the rapid aging of the population, as well as the demand for less invasive products and meaningful alternatives to pharmaceutical approaches for the treatment for chronic disease. While the medical technology field is only half as large as the world pharmaceutical market, it is growing at a much faster rate. While the top 25 companies dominate the field with more than 60% of industry sales, there are an estimated 20,000 medical technology companies worldwide, representing a collective market value in excess of $350 billion.

The growth of the medical technology field also has a very positive economic effect on states in the U.S., where nearly 400,000 people are employed in 6,000 companies. The Lewin Group estimates that for every medical technology job present in the average U.S. state, two more jobs, $1.12 in additional payroll and $.90 in sales revenue are created in that state.

With shorter product development cycles, lower capital requirements and simpler regulatory approval processes as compared to pharmaceutical and biotechnology companies, the medical technology field presents an excellent investment opportunity. Companies in this field have averaged gross margins of 60%, which is 15% higher than the average gross margins of the S&P 500. As a result, medical technology companies have managed to maintain relatively strong valuations, even in the current M&A environment.

Further, the medical technology sector is one arena where innovators and entrepreneurs do not have to be big to succeed. While the majority of these companies have fewer than 100 employees and offer a limited array of products, they are widely sought after by the larger public companies, such as Johnson and Johnson, St. Jude Medical, Medtronic and Boston Scientific, who have demonstrated that their primary means of holding and expanding their market position is through the acquisition of smaller companies. In many ways, they have effectively outsourced their research and development functions to these small enterprises, which have been primarily financed and nurtured by the venture capital industry.

Over the last decade, the advent of medical technology solutions to diagnose and treat cardiovascular conditions, diabetes, cancer, and orthopedic ailments, among others, has led to a burgeoning industry which has shown little sign of slowing down, even in a weakened economy. Moreover, medical devices and diagnostics are, for the first time, rapidly converging with information technology, telecommunications, remote monitoring, and a wide array of supportive healthcare services. As talk of healthcare reform increasingly turns to the importance of finding cost-efficiencies in the system, Psilos will continue to identify those diagnostic and therapeutic treatment technologies that help find disease earlier, when it is less expensive to treat, and which can be applied to produce a more favorable therapeutic outcome at a lower overall cost to the system.

For example, OmniGuide, a provider of carbon dioxide surgical lasers, has demonstrated that it can enable more effective ablation and excision of cancerous tumors in a less invasive manner. The result is a far more rapid treatment intervention (often saving several hours of expensive operating room time), a documented lower recurrence rate in key treatment areas as compared to other treatment modalities (and therefore less downstream treatment cost), and fewer costly negative side effects (due to the minimally invasive modality). It is precisely this combination of improved quality at lower cost that we believe will generate widespread product adoption and broad market opportunity in the coming healthcare economic cycle.

Another excellent example is SpineMatrix, a spinal imaging company that has developed CERSR ("Computerized Electrophysiological Reconstruction of Spinal Regions") for non-invasively evaluating low back physiology to accurately determine the origin of low back pain and injury. Current diagnostics are highly inaccurate, often physically invasive and frequently result in unnecessary and failed spine surgeries and related procedures and thus increased and unnecessary costs to the healthcare system (it is estimated that 10%-40% of the $90 billion spent in back surgery is unnecessary or unsuccessful). CERSR aids the physician in rapidly and accurately diagnosing the true source of lower back pain to significantly improve patient outcomes and reduces total health care costs by directing the lower back pain patient to the appropriate diagnostic, therapeutic or surgical treatment.

About Psilos Group

Psilos Group (www.psilos.com) is a venture firm investing growth capital in the healthcare economy. The firm believes that successful healthcare innovations must reduce cost, improve quality and align incentives across payers, providers and patients. Founded in 1998, Psilos has $577 million under management and has invested in 38 companies across three markets – healthcare services, healthcare IT and medical devices. Marquee portfolio companies include ActiveHealth, AngioScore, Click4Care, Definity Health, ExtendHealth, OmniGuide and Triveris.

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