

MII INVESTMENT MEMO



To: McIntire Investment Institute Managers  
From: James Rogers  
Subject: Long Position - Sepracor  
Date: December 1, 2008

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Sepracor, Inc. (NASDAQ: SEPR)  
Recommendation - Long  
December 1, 2008

**Company Summary**

Sepracor is a Massachusetts-based pharmaceutical company that develops drugs for respiratory and central nervous system ailments. It currently markets four medications and receives royalty payments from sales of two allergy prescriptions. Sepracor has asthma and COPD, anxiety, epilepsy, and depression treatments in its drug pipeline.

**Financial Information**

Exhibit I: Key Financial Information

	Sepracor	Industry Mean
Return on Equity	105.33%	-12.17%
Gross Profit Margin	89.95%	66.19%
Net Profit Margin	33.40%	-110.45%
Total Debt/Total Capital (MRQ)	52.61%	27.96%
Quick Ratio	2.0	3.02

Exhibit II: Sepracor Share Performance

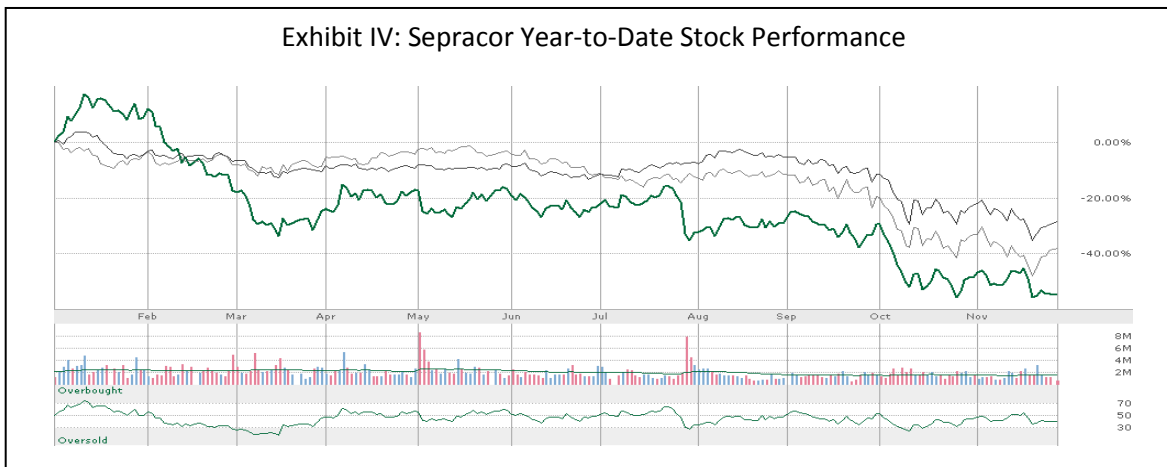
Share Price (Close: Nov. 28)	11.76
52-Week Trading Range	10.39 - 30.60
Market Capitalization	1.3B
P/E Ratio	3.23
PEG Ratio	0.27
EPS	3.64
Short Interest	4.77% of float

Sepracor released 3Q results on October 28 and reported a 4.2% increase in total revenues for the nine months ended September 30, compared to the same period in 2007. Sepracor has greatly increased research and development (R&D) funding. Through Q3 in 2008, it spent \$187,542,000 on R&D compared to \$135,384,000 spent through Q3 in 2007.

As shown by its profit margins, Sepracor has strong cash flows from its existing drug pipeline. Its P/E ratio is well below the industry average and its PEG ratio is particularly attractive. Thus, Sepracor has strong cash flows and positive growth prospects due to its drug pipeline.

Sepracor derives 49% of its revenue from Lunesta, an insomnia medication, and 39% of its revenue from Xopenex, an asthma treatment. Since its release in 2005, Lunesta has provided strong revenue for Sepracor. Although it saw a year-to-year decrease in the most recent quarterly earnings, Lunesta is still a steady revenue generator. Likewise, Xopenex and Xopenex HFA have strong presences in the asthma market. Brovana, which is another respiratory medication, was released late last calendar year and has seen strong revenue growth since then. It currently accounts for approximately 6% of revenue, but should account for a larger portion of Sepracor's revenue as it gains greater market share.

Despite its steady revenues and solid growth potential, Sepracor has underperformed the market year-to-date. Exhibit IV compares its performance to the Dow Jones Industrial Average (top line) and S&P 500 (middle, light gray, line). Overall, I believe Sepracor has been oversold and that it is an appealing long position.



## **Investment Thesis**

Sepracor is a compelling long position because it has a strong existing drug portfolio and a promising drug pipeline. Furthermore, it is undervalued relative to its peers and consistently beats market earnings expectations. Finally, Sepracor is well-positioned to benefit from developing trends in the pharmaceutical industry.

### *(I) Sepracor has a Strong Drug Portfolio*

Sepracor currently markets four drug treatments. Lunesta accounts for 49% of its revenues and has the highest profit margins of all drugs marketed by Sepracor. Lunesta is an insomnia medication that has seen decreasing revenues over the past four quarters due to increasing competition from other brand drugs. However, Lunesta has a competitive advantage because it is the only insomnia medication approved for long-term use by patients. Its competitors cannot be used for more than two consecutive weeks because of their addictive potential.

In addition to this competitive advantage, Lunesta also has very positive growth prospects. Sepracor submitted a drug application to the European Medicines Agency that if approved will permit Lunesta to be sold in the European Union (EU) under the name Lunivia. On October 24, the Committee for Medicinal Products for Human Use, a preliminary review board, gave a positive opinion on Lunivia. This recommendation will be considered by the European Medicines Agency as it reviews Lunivia's application. It is likely the EMA will approve Lunivia considering the drug's positive recommendation from the preliminary review and its preexisting approval by the FDA. If approved, Lunivia will be the first insomnia medication safe for long-term use to be marketed in the EU. This opportunity presents significant growth potential for Sepracor because the EU insomnia market is comparable in size to America's insomnia market.

Additionally, Sepracor recently completed a Phase IV trial investigating Lunesta's efficacy with elderly patients. Trial subjects experienced better daytime function after taking the drug over a 12-week period. The number of naps and total daily nap time both decreased due to Lunesta use.

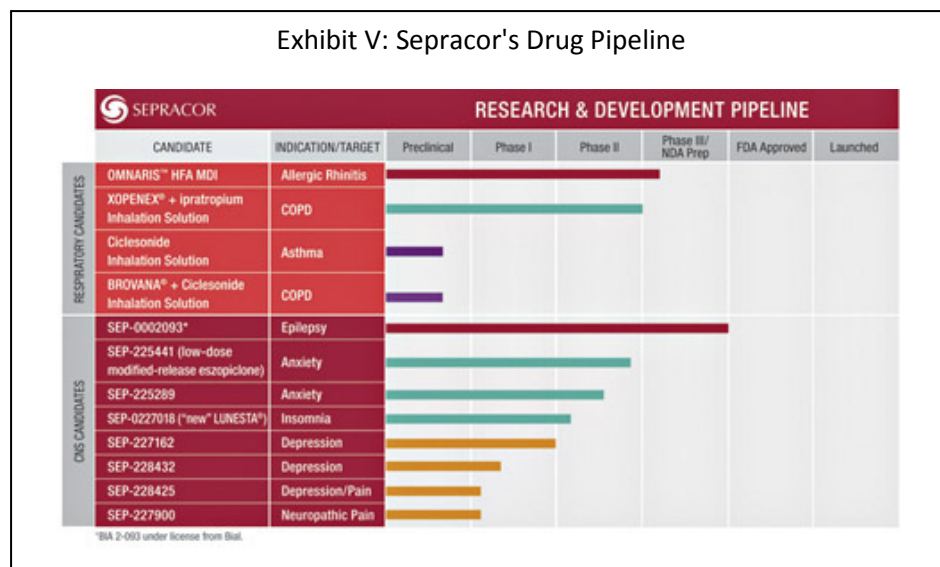
These findings could spur increased sales for Lunesta as doctors prescribe the drug to more elderly patients. Insomnia is a common condition among the elderly.

In addition to Lunesta, Sepracor also markets asthma and COPD treatments. Xopenex and Xopenex HFA treat and prevent bronchospams. Both drugs generate steady revenues for Sepracor but have little growth potential. In contrast, Brovana is an inhalation solution with great growth potential. It is administered twice-daily to COPD patients with bronchoconstriction and was released last calendar year. Since then, Brovana has experienced strong revenue growth. Its Q3 2008 revenues were \$14.8 million compared to \$2.4 million for Q3 2007. Such growth should be sustained as Sepracor expands marketing of Brovana and the treatment's reputation becomes solidified among healthcare providers.

*(II) Sepracor has a Promising Drug Pipeline*

Sepracor's developmental drugs (shown in Exhibit V) are focused on growing areas that are covered by insurance and experiencing increased demand. Sepracor's most advanced drug prospect is SEP-0002093, an epilepsy treatment that just completed Phase III trials and will be submitted for FDA approval in approximately three months. European regulators are already reviewing SEP-0002093. Results from the drug's most recent trial were promising with researchers concluding that the treatments "significantly reduced the frequency of partial seizures in patients with refractory partial epilepsy, in combination with other anti-epileptic agents." Additionally, the drug improved patient quality of life by reducing the frequency of partial seizures and intensity of depressive feelings. If approved, SEP-0002093 could be very profitable because it is easier to administer and offers more seizure control than current treatments.

Sepracor also has two central nervous system drugs in Phase II development. SEP-225441 is an anxiety treatment that hopes to decrease anxious behavior without acting as a sedative. It could also treat panic disorder. The results of a 400 patient study involving SEP-225441 will be released in Q1 2009. Sepracor's second Phase II prospect is the anxiety drug SEP-225289. Clinical results from its current study are expected by the end of Q2 2009. Thus far, SEP-225289 has shown promising results.



Overall, Sepracor's drug pipeline is diversified with central nervous system (CNS) and respiratory candidates in Phases I, II, and III of development. It has three advanced CNS drugs that treat the high demand conditions of epilepsy and anxiety. If successfully developed, approved, and marketed, these drugs will provide significant revenues for Sepracor.

*(III) Undervalued Relative to Its Peers*

Exhibit VI shows Sepracor's profit margin and PEG are much better than its peers. Yet, Sepracor has the lowest P/E ratio by far. Thus, its growth prospects are steeply discounted and it is undervalued relative to its peers.

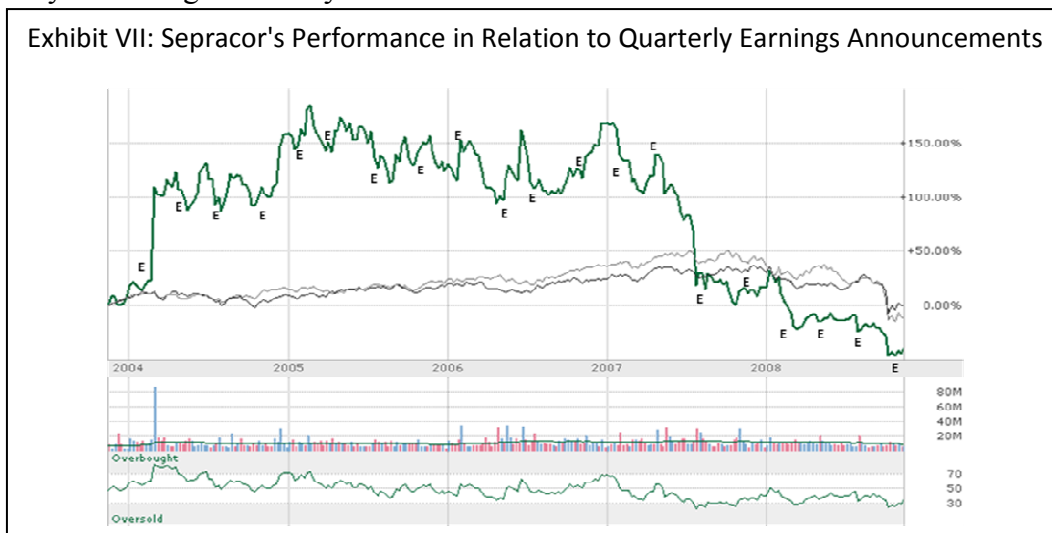
Exhibit VI: Comparison of Sepracor and Its Pharmaceutical Peers

	Sepracor	Inverness	MDS Inc.	Biovail
Share Price (11/28 close)	\$11.76	\$17.57	\$7.04	\$8.55
Market Cap.	\$1.3B	\$1.3B	\$852.5M	\$1.4B
Total Revenue (TTM)	\$1.3B	\$1.5B	\$1.3B	\$779.6MM
Net Profit Margin	33.40%	-3.60%	2.50%	6.10%
P/E Ratio	3.23	n/a	26.23	28.57
PEG Ratio	0.27	n/a	1.58	n/a

*(IV) The Market Regularly Underestimates Sepracor's Performance*

While analyzing Sepracor's earnings reports, I found that consensus estimates issued by Wall Street analysts for 11 of the past 14 quarters have underestimated Sepracor's results. This illustrates that analysts perennially underestimate the strength of Sepracor's drug portfolio and robust nature of its growth. As a result, I do not believe that Sepracor's promising drug pipeline and potential access to new markets for existing drugs are fully priced in.

Exhibit VII shows that the market also underestimates Sepracor. This chart compares Sepracor's earnings reports to its share performance from 2004 to the present. Sepracor often declines in value leading up to an earnings report, and then nicely rebounds following the typically higher than expected results. Thus, with few exceptions since 2004, Sepracor's earnings announcement has acted as a quarterly trough for its stock price. This trend has leveled off somewhat in 2008, and is likely due to high volatility in the overall market.



## *(V) Current Conditions in the Pharmaceutical Industry*

As described by my VAR contacts, significant barriers to entry exist in the pharmaceutical industry and these barriers help insulate Sepracor from increased competition. Furthermore, Big Pharma companies, which currently compete with Sepracor, have shrinking drug pipelines, and are increasingly outsourcing their R&D function to startups. However, the credit crunch and global recession have impaired startups' ability to attract venture capital, and as a result, many drug ideas are underfunded or unfunded. Sepracor can self-finance its R&D for promising projects while its competitors are unable to pursue similar drugs. Finally, Big Pharma companies are likely to increase mergers and acquisition (M&A) activity as they try to replenish pipelines. Sepracor is an attractive target because of its diversified pipeline. Sepracor's share price would greatly increase if a deal were rumored or announced.

### **Risks**

Sepracor's diverse pipeline presents many opportunities, but also poses more immediate risks. Its R&D expenses could increase as the company advances anxiety treatments to Phase III research and New Drug Application. A FDA rejection would hurt Sepracor's share price and drug pipeline, while also weakening its reputation.

Additionally, patent expirations are a risk because they allow generic drugs to enter the market and decrease Sepracor's revenue stream from existing drugs. Finally, operating costs have diminished Sepracor's profitability in past quarters and are something to monitor as it develops and markets new medications.

### **Catalysts**

Several catalysts exist that could significantly increase Sepracor's share price. FDA or European approval of a new drug would give Sepracor regulatory permission to begin marketing a developed treatment. Likewise, European approval of Lunivia would serve as a catalyst. Additionally, promising results from Phase II or III laboratory tests would increase the stock price and raise expectations of a New Drug Application's approval. Finally, Sepracor could benefit from a M&A stock price premium if takeovers within the industry increase as expected.

### **Value Added Research**

*Dr. Kim Whitten - Director of Clinical Development, Diffusion Pharmaceuticals*

Dr. Whitten discussed the financial costs related to drug R&D. She noted that the clinical development process for one drug candidate can cost between \$20.1 million and \$601 million. These costs present significant barriers to entry for pharmaceutical startups. In contrast, established mid-cap pharmaceutical companies like Sepracor are able to finance such development with their cash flow from existing drugs.

*Jacqueline Barrows - Clinical Trials Manager, Medical Device Consultants*

Ms. Barrows told me that in addition to being financially costly, clinical development also takes an average of 10 years. She noted that one of the largest hurdles in the drug development process is gaining FDA approval. She said that 75% of all New Drug Applications, which must be approved before a drug can be marketed, are eventually approved. However, very few

applications are approved on the first review cycle. She said the FDA review process takes approximately a year and focuses on a drug's safety profile, labeling, and results from clinical trials. Thus, the development process itself and regulatory restraints are further barriers to entry.

*Dr. Alev Erisir - Director of Cognitive Science, University of Virginia*

Dr. Erisir is a research scientist and discussed current trends in government funding for medical research. He noted that government funding has steadily decreased over the past five years and said the incoming Obama administration has given no indication that it will increase research aid. Dr. Erisir noted that many pharmaceutical startups depend on government grants to fund their research projects. Thus, one source of startup funding has been steadily decreasing and is unlikely to reverse course in the near term. This trend heightens the financial barriers to entry faced by pharmaceutical startups and further insulates Sepracor from emerging competition.

*Dr. Shaharyar M. Khan, Chief Scientific Officer, Gencia Corporation*

Dr. Khan said that the central nervous system “is a major area of development, but it is significantly hindered by a lack of understanding of CNS disorders, a lack of good animal models to test potential therapeutics for efficacy and the safety issues associated with chronic dosing.” Thus, Sepracor's three Phase II and III CNS candidates are well-positioned because they have passed many of the initial scientific hurdles related to CNS clinical development. These scientific hurdles also serve as a barrier to entry for the development of competing treatments.

*Dr. Yilong Ma, Research Scientist, New York University Center for Neurosciences*

Dr. Ma also researches CNS conditions and commented on epilepsy, anxiety, and depression trends. He noted that epilepsy affects a huge demographic and that currently no dependable treatments for epileptic seizures exist. Additionally, Dr. Ma said that demographic trends are likely to result in a larger market for anxiety and depression medications. He remarked that “anxiety and depression may become more prevalent as life expectancy increases.” Current anxiety and depression treatments have mixed results and unfavorable side effects. Overall, Dr. Ma's insight shows that Sepracor's CNS candidates target a growing market in health care.

*Dr. Sharon Esau - Associate Professor, University of Virginia Medical School*

Dr. Sharon Esau, a physician at the UVa Health System, commented on Sepracor's respiratory drugs. She was familiar with Sepracor, but stated that “no pharmaceutical company is really any better than others” in the eyes of healthcare providers. That said, Dr. Esau believes that Xopenex is an effective respiratory treatment because “it works better in patients who have tachyarrhythmias,” a fast heart rate condition. Dr. Esau added that Xopenex “seems to cause less shakiness for some patients.” However, these benefits come at a cost, as Dr. Esau noted that Xopenex is slightly more expensive than comparable treatments.

Finally, Dr. Esau said that about 10% of the population has asthma, and this number is expected to increase as air quality diminishes. She noted that demand for inhalation solutions and steroids is likely to increase as more people require regular asthma treatment. Thus, like its CNS candidates, Sepracor's respiratory drugs are targeted to an area of high demand and need.

*Dr. John L. Gainer - Co-Founder and Chief Scientific Advisor, Diffusion Pharmaceuticals*

Dr. Gainer is a former professor at the University. He left nearly a decade ago and founded Diffusion Pharmaceuticals, a startup in Charlottesville with a dozen employees. Dr. Gainer discussed his experiences founding Diffusion, current conditions in the industry, and developing trends. He founded Diffusion in 2000 after spending five years trying to get a patent for a chemical compound he developed. He noted that the patent process was "very expensive because of legal fees." It was also a lengthy process because his compound was novel and required extensive investigation by the Patent Office. Dr. Gainer said that ironically it is harder for truly novel inventions to gain approval "because the Patent Office has nothing to lean on and no precedents." Thus, the patent process is a legal barrier to entry that reduces the capital available to startup pharmaceuticals. Sepracor is immune from these difficulties because of its scale and ability to access new compounds through strategic partnerships with other pharmaceutical companies.

Dr. Gainer said that Diffusion began in a business incubator with only three employees and noted that "the first year we didn't have enough money to do anything." The startup relies on government grants and angel investors for its funding. Dr. Gainer said Diffusion has avoided venture capital funds "because you give up a lot of control when you deal with those firms." He noted that most startups trade seats on their Board of Directors for venture capital money. Dr. Gainer said that investors can obstruct clinical development as they try to reduce costs and develop profitable drugs quickly.

Finally, Dr. Gainer commented on trends in the industry. He noted that Big Pharma companies are "eliminating their research and development teams because their pipelines are drying up." Indeed, large cap pharmaceutical companies like Pfizer and Merck have eliminated hundreds of research positions over the past six quarters as they reduce R&D expenses and face increasing competition from generic drugs. According to Dr. Gainer, Big Pharma companies are increasingly outsourcing their research functions to startups and mid-cap firms. Finally, he noted that the industry overall has seen a decrease in drug development. Last year there were only 28 New Drug Applications filed with the FDA.

Thus, a vise scenario is developing in the industry. The traditional engines of innovation, Big Pharma companies, have dwindling drug pipelines and are reducing their R&D functions. Meanwhile, the emerging engines of innovation, startup firms, are unable to fund their projects due to unfavorable credit markets and a decrease in government funding. As a result, mid-cap companies like Sepracor are perfectly positioned to take advantage of this environment. Sepracor has strong cash flows from its existing drug portfolio, and can use this revenue to finance promising R&D. Sepracor's position will become even more favorable as the number of New Drug Applications continues to decrease and significant barriers to entry prevent many startups from entering the industry. Thus, Sepracor is well-positioned to profit from its promising drug pipeline due to a lack of viable competitors in the pharmaceutical industry.

*Matthew W. Hantzmon - Vice President for Business Development, Diffusion Pharmaceuticals*

Mr. Hantzmon leads Diffusion's business operations and discussed startup failure rates, financing trends in the industry, and the possibility for increased M&A activity. Prior to working at Diffusion, Mr. Hantzmon helped found two alternative energy startups. He noted that

"pharmaceutical startups have higher than average failure prospects" due to the significant barriers to entry they face. He also said that financing for startups is usually tied to meeting research benchmarks, and consequently if a drug candidate fails in Phase II trials, for example, the startup will often be forced to dissolve. Few startups can afford to finance more than one drug candidate, and consequently, are very vulnerable to disappointing laboratory results or unforeseen development problems.

Regarding current financing conditions, Mr. Hantzmon said that "In general the current market makes it more difficult to attract all kinds of financing" and "to get partnerships with other companies." He attended several venture capital presentations during Q2 and Q3 of this calendar year, and based upon these presentations, believes that "V.C. firms will reduce investment in startups over the next three to four quarters."

Finally, Mr. Hantzmon said that he expects M&A activity to greatly increase due to the vise effect I mentioned earlier. He said that Big Pharma has billions of dollars in cash reserves, and will likely employ this money "to selectively acquire companies that have promising Phase II and Phase III candidates." I asked him about Sepracor specifically and he said "I would not be surprised if a mid-cap company like Sepracor were acquired by a GSK [GlaxoSmithKline]." Sepracor's shares have been hurt by the overall market decline, and it is an appealing takeover target because of its diversified pipeline that has several candidates in advanced stages of development. I do not believe the market has priced in the possibility of more M&A activity because few investors and analysts are aware of these developing trends in the industry and their consequences.

## **Summary**

Sepracor is a compelling long position because of its strong drug portfolio and promising drug pipeline. Furthermore, Sepracor is undervalued relative to its peers and is perennially underestimated by the market. It is well-positioned to benefit from overall trends in the pharmaceutical industry. Unlike its Big Pharma competitors, Sepracor has a diversified and advanced drug pipeline. Unlike potential startup competitors that face significant barriers to entry, Sepracor has strong cash flow and is able to self-finance R&D. Thus, Sepracor is well-positioned within its industry, has strong growth potential, and is significantly undervalued.

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## **MII Suggestions**

1. I believe a centralized database of VAR contacts should be created and maintained by the Chief Information Officer. The database would include all VAR contacts used in analyst and election presentations. Long and short fund managers would have access to it, and could employ the database when reevaluating stock positions and assessing whether MII still has an edge.
2. I believe MII should replace the 2005 annual report with the most recent report on its website. I believe a special meeting concerning the annual report should be held each year where members can discuss the report with managers and gain a better understanding of MII's structure and the importance of annual reports for investment funds.