



GROSVENOR FINANCIAL PARTNERS, LLC

August 28, 2007

Price as of 8/28/07
\$1.35

Rating:
Accumulate

3- to 5-year Price Target \$7.00

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Company Description

Helix BioPharma is engaged in the exploration of new directions for preventing and treating cancer. Principal business activities currently focus on research and development of biopharmaceuticals. In addition, the Company earns revenues from its drug distribution business in Canada, international licensing arrangements, and

to a lesser extent, from contract research and development services.

HELIX BIOPHARMA CORP. (TSE: HBP)

Initial Report with a 3- to 5-year Price Target Price of \$7.00

As of 4/30/07 (except cap & range) | All \$ Figures Canadian

52-week range	\$1.01-\$2.75	Long-term debt	\$0
Shares Outstanding	36.4 million	Debt/Capital	NM
Insiders/Institutions	8%/12%	ROE Untaxed	NM
Public Float/Shares	29 million	Cash & Inv/Share	\$37
Market Capitalization	\$49 million	Book Value/Share	\$.43

FYE Jul	2005A	2006A	2007 A/E
EPS (SCDN)	Begins Aug 1, '04	Begins Aug 1, '05	Begins Aug 1, '06
Q1 Oct	(.05)	(.05)	(.04) A
Q2 Jan	(.06)	(.04)	(.05) A
Q3 Apr	(.04)	(.04)	(.04) A
Q4 Jul	(.13)	(.09)	(.09) E
Year	(.28)	(.22)	(.22) E

FYE Jul	2005A	2006A	2007 A/E
Revenues (\$mill)	Begins Aug 1, '04	Begins Aug 1, '05	Begins Aug 1, '06
Q1 Oct	0.978	0.906	0.826 A
Q2 Jan	0.883	1.105	0.882 A
Q3 Apr	0.984	1.099	0.864 A
Q4 Jul	0.887	0.855	0.851 E
Year	3.732	3.965	3.423 E

INVESTMENT SUMMARY

- **Helix BioPharma is a developmental stage company on the cusp of holding U.S. pre-IND meetings with the FDA regarding its two principal drugs: Topical Interferon Alpha-2b (follow-on pivotal trial) and DOS47 (Phase I).**
- **A Phase II clinical study of a stable topical form of interferon alpha-2b to treat conditions associated with Human Papilloma Virus (“HPV”) infection—optioned to Schering-Plough—has been completed.** This is scheduled to be followed on by a larger, double-blind U.S. study.
- **Helix’s U.S.-patented DOS47 leverages the urea cycle in the body to impart amplified anti-cancer effects.** The current area of focus is lung adenocarcinoma (glandular tissue-related tumor.) The pipeline for DOS47 will be expanded to include other indications.
- **Although Helix will require additional capital resources to fund R&D programs, the Company currently has sufficient cash to carry it through July 2008, at current burn rates.**
- **We believe that significant partnering opportunities lie ahead for Helix; and that it will be in an advantageous position to hand off its development products over time to large pharmaceutical companies hungry to bolster their pipelines.**

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- **We are initiating with a Buy rating and a 3- to 5-year price target of \$7.00 Canadian. (Please refer to our Valuation section, Page 6)**
- **The usual risks associated with small biotech companies are applicable: drugs that are promising in early trials fail to live up to expectations in later clinical phases; uncertainty in the flow of partnering and milestone payments; dilution from frequent financing; regulatory twists and turns; the company runs out of money.**

Topical Interferon Alpha-2b

This formulation has shown good potential for genital conditions referred to as cervical LSIL and AGW (please refer to note below). Helix announced completion of its first clinical study with Topical Interferon Alpha-2b on March 30th, 2007. This phase II study was conducted in Germany in 41 women with LSIL. A second phase II trial with the product, in patients with AGW is presently underway in Sweden, and will assess 120 female patients using a randomized, double-blind, placebo-controlled study design (60 patients to receive Topical Interferon Alpha-2b; 60 patients to receive placebo.) Both of these conditions are associated with contracting any of a variety of different strains of the human papilloma virus (HPV)—today’s most prevalent sexually transmitted infection.

There are presently no *pharmaceutical* treatment options for LSIL. Surgical methods are available; but these techniques carry significant side-effect potential, especially for women of childbearing age, including increased risk of abortion and premature labor. In the case of AGW, on the other hand, there are a variety of pharmaceutical and alternative therapies available to patients (e.g., ALDARA Cream, cryotherapy etc). Generally speaking, however, available therapies are associated with significant localized pain and/or irritation for the patient.

Helix’s objective with Topical Interferon Alpha-2b is to bring forth a powerful new means of treating HPV-induced lesions. Unlike most conventional therapies, the product is designed to

Note: LSIL stands for low-grade squamous intraepithelial lesions; AGW refers to ano-genital warts.



attack the underlying viral condition, rather than merely destroying the resulting visible lesion(s) it causes. Its advantages are summarized below:

- Topical
- Convenient, self-administration
- Painless
- Non-irritating
- Non-surgical
- Stimulates the body's immune system
- Able to treat both visible and sub-clinical lesions
- Offers a pharmaceutical option where none exists today for LSIL patients

In addition, Topical Interferon Alpha-2b is designed to be used in the privacy and convenience of one's home, which is expected to be very appealing to patients. By comparison, existing treatments for cervical lesions require invasive medical procedures in a hospital or clinical setting.

Helix believes that its specialized formulation is unique among today's dermal delivery vehicles in being able to offer a stable cream dosage form capable of delivering interferon alpha-2b into the skin. The main products that may offer noteworthy competition for Topical Interferon Alpha-2b as a treatment for Helix's primary therapeutic targets are emerging prophylactic vaccine therapies. Companies such as Merck and Co. and GlaxoSmithKline Inc. have developed vaccines that protect against infection from several specific subtypes of HPV. However, while prophylactic vaccination may prevent future generations from contracting certain HPV infections, it does not offer a therapeutic solution to millions of patients who already are or become infected. Presently over 2 million new cases of LSIL/AGW annually occur in the USA alone, which equates to a global market of some \$600 million plus. The market size would increase significantly if the product were used additionally for other potential indications.



L-DOS47

Lung cancer is now the leading form of cancer as well as the leading cause of death due to cancer for both men and women around the world. More people die each year of lung cancer than of colon, breast, and prostate cancers combined.

Treatment strategies today for patients with adenocarcinoma of the lung are unfortunately of limited effectiveness. If detected early, surgical removal of the cancerous tissue is a patient's best option today. In the cases of inoperable adenocarcinomas of the lung, treatment strategies consist of one or more of today's leading chemotherapeutic drugs for lung cancer (e.g. platinum therapy, Taxol®, Taxotere® and Gemzar®) used in combination with thoracic radiation therapy. Typically, these regimens relieve symptoms and, at best, delay progression of the disease for a short period, likely to be only several months.

Helix's L-DOS47 represents the first product candidate to be realized from Helix's patented technique of using the enzyme class *urease* or DOS47 to combat solid tumors. Just as L-DOS47 targets lung adenocarcinomas that affect the lung tissue, the Company envisions developing a host of additional DOS47-based therapeutics to target and treat other forms of cancer.

L-DOS47 is designed to offer a potentially revolutionary therapy for lung adenocarcinomas by leveraging the urea cycle in the human body to precipitate amplified anti-cancer effects. By changing the tumor microenvironment, disruption of the metabolism and structure of cancer cells is produced. This technique is utterly unlike the majority of cancer medications on the market or under development today. As such, L-DOS47 could have potential as both a single therapy or in chemotherapy regimens together with products that are otherwise challenged by the unique microenvironmental characteristics of tumors.



Helix is currently at the preclinical level of development for L-DOS47. To-date, a number of important steps have been completed, including the following:

1. *In vitro* / *in vivo* proof-of-concept studies with DOS47 enzyme class, per se
2. Licensing of a lung-cancer antibody from Canada's National Research Council
3. *In vitro* studies supporting adjunct chemotherapy effectiveness of L-DOS47
4. Human tissue structural studies with L-DOS47
5. Preliminary rodent and primate toxicology studies

The work program so far has demonstrated the potent cytotoxic effects of L-DOS47 against lung cancer cells *in vitro* along with the remarkable specificity of the compound for human lung adenocarcinoma cells in particular. Furthermore, *in vivo* safety and efficacy studies have shown L-DOS47 to be effective at doses below its maximum tolerated dose.

Based on the successful findings thus far, Helix believes that L-DOS47 could be expeditiously advanced to human clinical testing in lung adenocarcinoma patients, ideally starting in the U.S. Accordingly, Helix has contracted the services of expert U.S. and Canadian third-party service providers to assist with guiding and executing the remaining preclinical development work.

The target market for L-DOS47 appears to be in excess of \$1 billion globally. This figure is based on 90,000 cases per year in the U.S., and selling prices comparable to market comparators (e.g., Gemzar®, Taxol®, Taxotere® etc), and assumes a conservative market penetration rate.



Valuation

There are a number of biotech valuation models in use, but all have drawbacks and have consistently failed to deliver any reliable price expectations that tracked with reality in so volatile and subjective a market. Discounted Cash Flow, Decision Tree Analysis, Net Present Value, Single Discount Rates, Venture Capital Discount Rates, while not exactly black arts, have yielded models, which only on rare occasions and for very short periods of time, roughly correspond to prices in real time. As well, the biotech industry is very susceptible to general stock market sentiment, as well as perceived trends in drug regulation.

We speculate that the peak market sales for Helix BioPharma's two present drug formulations could be in the range of \$1.5 to \$2.0 billion. We derive these figures by use of estimated worldwide incidences of their respective medical indications, selling prices based on appropriate comparators, and conservative market penetration rates. With the exception of anti-infectives, whose pathology is well known, most drugs in their early clinical phases turn out to have appallingly low success rates. But considering the potential size of the markets involved, it is in our opinion more than an even bet that a large pharma company will get involved with either one or both of Helix's drugs. The market now accords Helix a \$49 million cap, which is only one thirtieth the potential market size for its developing drug portfolio (using the lower figure). Twice before in its history, Helix has sold at many multiples of its current price: at \$8, in late 2000, and over \$7 in mid-2003. It sold at over \$4 as recently as 18 months ago. The stock currently is selling at the very bottom of its past 7-year historical range, (please see the chart just below). Is it a justifiably cheap stock that has lost its research pizzazz? Or is this price just a lull in its market valuation cycle? We obviously think the latter, if we consider that both of Helix's drugs probe new dimensions in cancer therapy by being significantly more body-friendly, if you



will, and are not just me-too products. While it's not possible to determine a price objective based on traditional multiples of sales and earnings at this time, we strongly believe that there is substantial value in the current price of the shares relative to the prospects for its slender but nevertheless distinctive pharma pipeline.



Courtesy bigcharts.com