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**NEWS RELEASE**

## **HELIX BIOPHARMA CORP. ANNOUNCES FISCAL 2009 RESULTS**

(Aurora, Ontario) – Helix BioPharma Corp. (TSX, FSE: HBP / OTCQX: HXBPF) today announced financial results for the year ended July 31, 2009.

During the 2009 fiscal year, the Company continued to make progress with its development initiatives for its lead drug candidates, L-DOS47 and Topical Interferon Alpha-2b. The following are selected highlights during the 2009 fiscal year and subsequent to year-end.

### **FISCAL 2009 HIGHLIGHTS**

#### **DOS47/L-DOS47**

- A pre-IND meeting with the U.S. Food and Drug Administration (“FDA”) was held for L-DOS47 in which the FDA generally agreed with Helix’s proposed remaining non-clinical pharmacology and toxicology studies as well as its remaining GMP manufacturing program initiatives prior to IND filing.
- Helix announced plans to conduct a Phase I/II clinical study of non-small cell lung cancer (“NSCLC”) patients in Poland. Helix has been finalizing these plans with key opinion leader clinicians and contract research organizations in Poland. The study is expected to run concurrently with the U.S. Phase I trial in refractory solid tumor patients. The timing of both studies will be contingent on the timing of regulatory approvals of the trials as well as obtaining additional capital.

#### **Topical Interferon Alpha-2b**

- A pre-IND meeting with the FDA was held in which the FDA confirmed the acceptability of a Phase II/III, randomized, vehicle-controlled clinical trial as the next step in the compound’s clinical development plan for patients with cervical dysplasia. The FDA also confirmed Helix’s expectation that an additional well-controlled, Phase III confirmatory clinical trial will be required to establish efficacy and safety of the product for marketing authorization purposes. Helix intends to continue to make preparations to conduct a European Phase III trial for this purpose.
- The Phase II pharmacokinetic study is expected to complete the minimum 12 patients by the end of the third quarter of fiscal 2010.
- Enrollment in the ongoing Phase II clinical trial of Topical Interferon Alpha-2b in patients with anogenital warts (“AGW”) in Sweden and Germany is progressing on track. The Company expects the last patient to be enrolled on or around the end of the first quarter of fiscal 2010. The study has now enrolled over 93% of the required 120 patients.

#### **Financing**

- Completed a private placement financing on October 2, 2008 for gross proceeds of \$11,424,000.
- Completed a private placement financing on September 8, 2009 for gross proceeds of \$13,581,250.

#### **Other**

- Prof. Majewski, stepped down from the Board of Directors to assume the advisory role of European medical director, effective August 11, 2009.
- Prof. Kazimierz Roszkowski-Sliz was appointed to the Board of Directors on August 17, 2009.

## FINANCIAL REVIEW

For fiscal 2009, the Company recorded a net loss of \$14,102,000, which represents an increase of \$7,138,000 when compared to fiscal 2008. The net loss per common share for fiscal 2009 was \$0.27 and represents an increase of \$0.11 in loss per common share when compared to fiscal 2008. Product revenue contributed to the increase in revenue in fiscal 2009 and overall expenses were higher when compared to fiscal 2008 which mainly reflect higher research and development expenditures, stock-based compensation expense associated with stock options granted in the second quarter, lower interest income and a foreign exchange loss.

Total revenues in fiscal 2009 were \$3,841,000 and represent an increase of \$250,000 or 7.0% when compared to total revenues in fiscal 2008 of \$3,591,000. Product revenue contributed to the increase in revenue in fiscal 2009 when compared to fiscal 2008 and was offset slightly by a decrease in license fees and royalties.

Product revenue in fiscal 2009 totalled \$3,244,000 and represents an increase of \$292,000 or 9.9% when compared to product revenue in fiscal 2008 of \$2,952,000. Product sales of Orthovisc® grew in fiscal 2009 while Klean-Prep™ revenue remained relatively stable. License fees and royalties in fiscal 2009 totalled \$597,000 and represent a decrease of \$42,000 or 6.6% when compared to fiscal 2008. The decrease reflects lower Klean-Prep™ royalty revenue from Helsinn-Birex which was offset by the final payment from Lumera Corporation of US\$75,000 when it provided the Company with notice of termination of its sub-license agreement.

Cost of sales in fiscal 2009 and 2008 totalled \$1,516,000 and \$1,239,000, respectively. As a percentage of product revenues, cost of sales in fiscal 2009 and 2008 were 46.7% and 42.0%, respectively. In addition to some foreign exchange impact, cost of sales was also impacted by higher distribution costs. The increase in cost of sales, on a percentage, basis was mainly the result of lower average selling price per units sold of Orthovisc®. Lower pricing was offered on Orthovisc® to assist in customer retention for a scheduled launch of a new, single injection product in the first quarter of fiscal 2010.

Research and development expenditures in fiscal 2009 totalled \$10,322,000 and represent an increase of \$5,258,000 or 103.8% when compared to fiscal 2008. L-DOS47 and Topical Interferon Alpha-2b reflect an increase of 52.6% and 171.2%, respectively. The increase in research and development expenditures associated with L-DOS47, are primarily related to the scale-up manufacturing program and ongoing collaborative research initiatives in anticipation of furnishing product for future clinical testing. The increase in research and development expenditures associated with Topical Interferon Alpha-2b reflect the ongoing costs for the AGW Phase II clinical trial in Sweden and Germany in addition to scale-up manufacturing costs, preparatory work and start-up of the European Phase II pharmacokinetic study in patients with low-grade cervical lesions.

Operating, general and administration expenses in fiscal 2009 totalled \$3,917,000 and represent a decrease of \$31,000 or 0.8% when compared to fiscal 2008. The operating, general and administration expenditures include one time costs associated with the filing of a Form 20-F registration statement with the U.S. Securities and Exchange Commission, which became effective during the third quarter of fiscal 2009. Other expenditures included in operating, general and administration expenditures are costs associated with the implementation of a new financial reporting system and expenditures associated with capital raising initiatives. Offsetting some of the aforementioned increases in expenditures are lower wages and benefits from the foregoing of accrued vacation days by management during the current fiscal year and lower wages and benefits due to a one-time charge relating to the resignation of the Company's previous Chairman, and executive bonuses paid, in fiscal 2008.

Sales and marketing expenses in fiscal 2009 totalled \$969,000 and represent an increase of \$160,000 or 19.8% when compared to fiscal 2008. The increase mainly reflects higher sale agent commission resulting from higher product revenues along with increased advertising and promotional expenditures.

Amortization of capital assets in fiscal 2009 totalled \$274,000 and represents an increase of \$20,000 when compared to fiscal 2008. The higher amortization expense of capital assets in fiscal 2009 is the result of higher capital acquisitions in the current fiscal year.

Amortization of intangible assets in fiscal 2009 totalled \$12,000 and represents a decrease of \$4,000 when compared to fiscal 2008. The lower amortization expense of intangible assets was the result of the write-down of intangible assets in the fourth quarter of fiscal 2009.

Stock-based compensation expenses in fiscal 2009 totalled \$1,023,000 and represent an increase of \$979,000 when compared to fiscal 2008. The stock-based compensation expense in fiscal 2009 relates to the ongoing amortization of compensation costs of 2,070,000 stock options granted on December 17, 2008 over their vesting period. The stock options vested 25% on the date of grant and 25% at each anniversary date thereafter. The Company did not issue any stock options in fiscal 2008. The stock-based compensation expense for fiscal 2008 represents the ongoing amortization of compensation costs of stock options granted on June 30, 2005, over their vesting period.

Interest income totalled \$339,000 in 2009 and \$645,000 in fiscal 2008. The decrease in interest income in fiscal 2009 reflects lower interest rates earned on deposits resulting from the global financial crisis.

The Company recorded a foreign exchange loss of \$133,000 in fiscal 2009 and a foreign exchange gain of \$327,000 in fiscal 2008. Foreign exchange losses mainly reflect the lower Canadian dollar exchange rate relative to the US dollar with the largest impact related to the second and third quarters of fiscal 2009. Also impacting the foreign exchange loss in the year is the foreign currency translation of the Company's integrated foreign operation in Ireland. The net assets in Ireland consist mainly of cash and cash equivalents, denominated in Euro dollars, which are used to fund clinical trials of Topical Interferon Alpha-2b in Europe.

Impairment of intangible assets totaled \$98,000 in fiscal 2009 and \$nil in fiscal 2008. During the fourth quarter of fiscal 2009, the Company reviewed its capitalized intangible assets and determined that expected future cash flows may not exceed their carrying values. As a result, the carrying value of the related intellectual property became impaired and was written down.

Income tax expenses totalled \$18,000 in fiscal 2009 and \$153,000 in fiscal 2008. Income taxes are attributable to the Company's operations in Ireland.

## **LIQUIDITY AND CAPITAL RESOURCES**

Since inception, the Company has financed its operations from public and private sales of equity, the exercise of warrants and stock options, and, to a lesser extent, on interest income from funds available for investment, investment tax credits, and revenues from distribution, licensing and contract services. Since the Company does not have net earnings from its operations, the Company's long-term liquidity depends on its ability to access the capital markets, which depends substantially on the success of the Company's ongoing research and development programs.

At July 31, 2009 and 2008, the Company had cash and cash equivalents totaling \$14,494,000 and \$19,057,000, respectively. The \$4,563,000 decrease in cash and cash equivalents reflects a use of cash in operating activities of \$13,157,000 which includes a net loss for the year of \$14,102,000. Operating activities were financed from a private placement which closed on October 2, 2008 for net proceeds of \$9,659,000. Cash used in investing activities in the 2009 fiscal year total \$932,000 which predominately reflects purchases of research and development equipment. Effect of exchange rate changes on cash and cash equivalents in fiscal 2009 represent a foreign exchange loss of \$133,000.

At July 31, 2009 and 2008, the Company's working capital was \$15,296,000 and \$19,166,000, respectively.

On September 8, 2009, subsequent to Company's fiscal year ended July 31, 2009, the Company completed an additional private placement, issuing 6,625,000 units at \$2.05 per unit, for gross proceeds of \$13,581,250. Each unit consists of one common share and one common share purchase warrant, with each common share purchase warrant entitling the holder to purchase, subject to adjustment, one common share at a price of \$2.87.

Based on the Company's currently planned expenditures and assuming no unanticipated expenses, the Company estimates its cash reserves will be sufficient to meet anticipated cash needs for working capital and capital expenditures for the next twelve months. The Company has no external sources of liquidity such as bank lines of credit. The Company will require future additional financing to carry out its business plan. The market for both debt and equity financings for companies such as Helix has always been challenging, and the global economic downturn and credit crisis have added further challenges. There can be no assurance that a financing, whether debt or equity, will be available on acceptable terms or at all.

The Company's consolidated fiscal 2009, 2008, and 2007 financial statements are summarized below.

<i>Consolidated Statements of Operations</i> <i>(thousand \$, except for per share data)</i>			
	2009	2008	2007
<b>Revenue:</b>			
Product revenue	3,244	2,952	2,764
License fees & royalties	597	639	512
Research and development contracts	-	-	148
	<u>3,841</u>	<u>3,591</u>	<u>3,424</u>
<b>Expenses:</b>			
Cost of sales	1,516	1,239	1,139
Research and development	10,322	5,064	4,116
Operating, general and admin	3,917	3,948	3,570
Sales and marketing	969	809	848
Amortization of intangibles	12	16	159
Amortization of capital assets	274	254	287
Stock-based compensation	1,023	44	47
Interest income	(339)	(645)	(496)
Foreign exchange loss (gain)	133	(327)	(9)
Impairment of intangibles	98	-	1,332
	<u>17,925</u>	<u>10,402</u>	<u>10,993</u>
Loss before income taxes	(14,084)	(6,811)	(7,569)
Income taxes	18	153	105
Loss for the year	<u>(14,102)</u>	<u>(6,964)</u>	<u>(7,674)</u>
<b>Loss per share:</b>			
Basic	(0.27)	(0.16)	(0.22)
Diluted	(0.27)	(0.16)	(0.22)

<i>Consolidated Statements of Cash Flows (thousand \$)</i>			
	2009	2008	2007
<b>Cash provided by (used in):</b>			
Loss for the year	(14,102)	(6,964)	(7,674)
<b>Items not involving cash:</b>			
Amortization of capital assets	274	254	287
Amortization of intangibles	12	16	159
Deferred lease credit	123	-	-
Stock-based compensation	1,023	44	47
Impairment of intangibles	98	-	1,332
Foreign exchange loss (gain)	133	(327)	(9)
	<u>(12,439)</u>	<u>(6,977)</u>	<u>(5,858)</u>
Change in non-cash working capital	(718)	(20)	(221)
Operating activities	<u>(13,157)</u>	<u>(6,997)</u>	<u>(6,079)</u>
<b>Financing activities</b>			
Investing activities	9,659	14,614	6,480
Effect of exchange rate changes on cash and cash equivalents	(932)	(266)	6,577
	<u>(133)</u>	<u>327</u>	<u>9</u>
<b>Cash and cash equivalents:</b>			
Increase/(decrease) in the year	(4,563)	7,678	6,987
Beginning of the year	19,057	11,379	4,392
End of the year	<u>14,494</u>	<u>19,057</u>	<u>11,379</u>

<i>Consolidated Balance Sheet (thousand \$)</i>		
	2009	2008
<b>Current assets:</b>		
Cash and cash equivalents	14,494	19,057
Accounts receivable	1,053	349
Inventory	858	458
Prepaid and other	1,049	446
	<u>17,454</u>	<u>20,310</u>
<b>Non current assets</b>	<u>1,865</u>	<u>1,356</u>
<b>Total assets</b>	<u>19,319</u>	<u>21,666</u>
<b>Current liabilities:</b>		
Accounts payable & accruals	1,299	598
Accrued liabilities	834	546
Deferred lease credit	25	-
	<u>2,158</u>	<u>1,144</u>
<b>Non current liabilities</b>	<u>98</u>	<u>-</u>
<b>Total liabilities</b>	<u>2,256</u>	<u>1,144</u>
<b>Shareholders' equity</b>	<u>17,063</u>	<u>20,522</u>
<b>Total liabilities and shareholders' equity</b>	<u>19,319</u>	<u>21,666</u>

The Company's complete 2009 Consolidated Financial Statements, Management's Discussion and Analysis and Annual Information Form are being filed today with Canadian securities regulatory authorities and will be available at SEDAR at [www.sedar.com](http://www.sedar.com).

## About Helix BioPharma Corp.

Helix BioPharma Corp. is a biopharmaceutical company specializing in the field of cancer therapy. The Company is actively developing innovative products for the prevention and treatment of cancer based on its proprietary technologies. Helix's product development initiatives include its novel L-DOS47 new drug candidate and its Topical Interferon Alpha-2b. Helix is listed on the TSX and FSE under the symbol "HBP" and the OTCQX International Market under the symbol "HXBPF".

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## Forward-Looking Statements and Risks and Uncertainties

This News Release contains certain forward-looking statements and forward-looking information, within the meaning of applicable securities laws, regarding the Company's plans for future clinical trials for L-DOS47 and Topical Interferon Alpha-2b; the timing of completion of the Phase II pharmacokinetic study for the minimum 12 patients and of completion of enrolment for the Phase II AGW trial of Topical Interferon Alpha-2b; the timing of a future Phase I/II clinical study for L-DOS47 in Poland; sufficiency of the Company's cash reserves and expected cash flow from operations; and other information in future periods, which statements and information can be identified by the use of forward-looking terminology such as "plans", "expected", "intends", "estimates", "next", "anticipated", "developing", "will" or variations thereon, or comparable terminology referring to future events or results. Although Helix believes that the expectations reflected in such forward-looking statements and information are reasonable, such statements and information involve risks and uncertainties, and undue reliance should not be placed on such statements and information. Certain material factors or assumptions are applied in making forward-looking statements and providing forward-looking information, including, but not limited to, patient recruitment rates and the timely and successful completion of ongoing clinical trials, GMP manufacturing and other activities; the timely provision of services by third parties; future revenue, costs and regulatory approvals. Important factors that could cause actual results to differ materially from these forward-looking statements and information include, without limitation, the Company's continuing need for additional capital, which may not be available in a timely manner or at all and which if not obtained will have a material adverse impact on the Company and its ability to continue, or if not obtained in a timely manner, may result in the Company's having to discontinue or delay one or more of its product development programs or other initiatives; uncertainty whether Topical Interferon Alpha-2b or L-DOS47 will be successfully developed and commercialized as a drug or at all; the risk that the FDA is not bound by its pre-IND meetings; uncertainty whether any of the timelines mentioned in this press release will be achieved; Helix's dependence on its third party service providers, including without limitation, contract research organizations, contract manufacturing organizations, clinical trial consultants, collaborative research consultants, regulatory affairs advisors, and others, whose performance and interdependence can critically affect the Company's performance and the achievement of its milestones; uncertainty whether any of the clinical trials referred to in this news release will be approved, initiated or completed as planned or at all or will achieve expected results; the need for additional clinical trials, the occurrence and success of which cannot be assured; product liability and insurance risks; research and development risks, including the possibility that further challenges may arise in connection with the scale-up manufacturing of L-DOS47 or Topical Interferon Alpha-2b, or in connection with the German pharmacokinetic study; the risk of obtaining negative findings or factors that may become apparent during the course of research or development which may result in the discontinuation or delay of the research or development projects; the risk of technical obsolescence; the need for further regulatory approvals, which may not be obtained in a timely matter or at all; intellectual property risks, including without limitation, the risk that three patents for Topical Interferon Alpha-2b will expire in 2013 and no additional patent may be issued, that patent applications may not result in issued patents, that issued patents may be circumvented or struck down, and the risk of potential claims of infringement by the Company of third party intellectual property rights; marketing/manufacturing and partnership/strategic alliance risks; the effect of competition; uncertainty of the size and existence of a market opportunity for Helix's products; the risk that the Company's supplier for Topical Interferon Alpha-2b may not continue to provide the Company with interferon alpha-2b or exercise its commercialization option, which would have a negative effect on the further development of the drug candidate and on the Company; Helix's dependence on its licensor of the L-DOS47 antibody; the need to secure new strategic relationships, which is not assured, to commercialize L-DOS47 and any other drug candidates which may arise out of DOS47; the risk of unanticipated expenses or failure to achieve expected revenue; and the risk of changes in business strategy or development plans. Certain of these risks and uncertainties, and others affecting the Company which could cause actual results to vary materially from current results or those anticipated in forward-looking statements and information, are more fully described in the Company's latest MD&A, Form20-F and other reports filed with the Canadian Securities Regulatory Authorities and the U.S. SEC from time to time at [www.sedar.com](http://www.sedar.com) and [www.sec.gov/edgar.shtml](http://www.sec.gov/edgar.shtml), respectively. Forward-looking statements and information are based on the beliefs, assumptions, opinions and expectations of Helix's management at the time they are made, and Helix does not assume any obligation to update any forward-looking statement or information should those beliefs, assumptions, opinions or expectations change, except as required by law.