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June 12, 2014 NEWS RELEASE

# HELIX BIOPHARMA CORP. ANNOUNCES FISCAL Q3 2014 RESULTS

(Aurora, Ontario) – Helix BioPharma Corp. (TSX, FSE: "HBP"), a biopharmaceutical company developing drug candidates for the prevention and treatment of cancer, today announced financial results for the three and ninemonth periods ended April 30, 2014 and 2013.

## RESEARCH AND DEVELOPMENT UPDATE

#### L-DOS47

On May 14, 2012, the Company commenced clinical site initiations and patient recruitment activities for its European Phase I/II clinical study of L-DOS47 in Poland ("LDOS002"). Since the dosing of the first patient in Cohort 1 on October 23, 2012, the Company remains on target to achieve its milestone of completing Cohort 8 of the Phase I component of the European Phase I/II clinical study by the summer of 2014. As previously disclosed, the total number of patients to be enrolled in the study will depend on how many escalating dose levels are required to reach maximum tolerated dose ("MTD"). The Company originally estimated that MTD would be reached after enrolling eight cohorts of three patients. Management also originally assumed that there would be two dose limiting toxicity events requiring a further six patients to be enrolled, for a total of up to 30 patients by the time the study dosed patients in Cohort 8.

On October 15, 2013, the Company announced the completion of an interim data review of the first four cohorts for this study. The release stated that L-DOS47 was well tolerated for all patients treated within all cohorts. None of the treatment related adverse events reported to date has met the definition of a dose-limiting toxicity. Adverse events reported as of that date are those normally expected for the population under study. The Company plans to conduct a second interim data review of LDOS002 that will commence following the completion of the second treatment cycle of Cohort 8 patients. The Company has initiated a protocol amendment that would allow sites to continue dose escalation for the Phase I component of the LDOS002 study in the event MTD is not reached by the end of Cohort 8. Without regulatory approval for the protocol amendment, the Company will not be able to enroll patients beyond Cohort 8.

The Company has met or exceeded certain expectations in executing the clinical development plan for L-DOS47. Specifically, the Company has:

- Completed the enrollment of Cohort 8 of the Phase I component of study LDOS002 in advance of its previously disclosed milestone.
- Applied for a new US Phase I Investigational New Drug ("IND") trial and on April 22, 2014 announced the approval by the FDA to commence a study for an L-DOS47 Phase I, open label, dose escalation study in combination with standard doublet therapy of pemetrexed/carboplatin in patients with Stage IV recurrent or metastatic non-squamous non-small-cell lung cancer ("NSCLC").

Regarding the Clinical Trial Application ("CTA") filing in Canada for the approval and commencement of a Phase I study for L-DOS47 in combination with the chemotherapy drug vinorelbine in patients with metastatic NSCLC and metastatic breast cancer, the Company has had discussions with Health Canada. In these discussions, Heath Canada requested additional information regarding the proposed trial and in order to properly address Health

Canada's questions in the most efficient manner, the Company on June 11, 2014 voluntarily withdrew the CTA submission and will be resubmitting the CTA along with any additional information, as soon as possible.

The Company's cash position as at April 30, 2014 of \$2,832,000 is not sufficient to see the entire European Phase I/II clinical study in Poland, nor any part of the U.S. Phase I study or, if approved, the Canadian Phase I study, through to completion. The Company has previously disclosed that it expected to have sufficient cash to complete the Phase I portion of the European clinical study, provided the Company did not experience any unforeseen challenges and expenditures. The Company is currently dosing patients in Cohort 8. The Company originally estimated that the Phase I component of this study would enroll eight cohorts, as this was the number of cohorts estimated to be required to reach MTD. However, in the event the Company does receive regulatory approval for the protocol amendment but does not reach MTD at Cohort 8 as originally estimated, the Company will not have sufficient funds to complete the European Phase I trial for L-DOS47 in Poland.

### Topical Interferon Alpha-2b

After agreeing to terminate the contractual arrangement with Merck Sharp & Dohme Corp ("Merck"), the Company's primary and ongoing focus, as it relates to the Topical Interferon Alpha-2b program, has been on sourcing and qualifying alternative interferon alpha-2b raw material samples, and finding suitable strategic partner(s) who would be willing to license or acquire the product and supports the remaining development costs through to commercial launch. As a result, the Company has hired an outside consultant to assist it in finding a suitable strategic partner(s).

To date, the Company has completed preliminary quality testing, comparing alternate raw material samples to its approved drug substance specification and a potential new supplier of the interferon alpha-2b raw material necessary to formulate the product candidate has been identified. However, further quality testing and evaluation of this material and its supplier, as well as negotiation of supply terms acceptable to the Company and receipt of necessary regulatory approvals will be necessary before the Company will be in a position to definitively verify raw material comparability with the interferon alpha-2b originally supplied by Merck.

The continuation of the Topical Interferon Alpha-2b program more generally is dependent on a strategic partner(s) providing additional funding.

# **FINANCIAL REVIEW**

The Company recorded a net loss and total comprehensive loss of \$2,109,000 and \$6,878,000, respectively for the three and nine-month periods ended April 30, 2014 for a loss per common share of \$0.03 and \$0.10, respectively. For the comparative three and nine-month periods ended April 30, 2013, the Company recorded net loss and total comprehensive loss of \$2,224,000 (loss per common share of \$0.03) and net income and total comprehensive income of \$368,000 (earnings per common share of \$0.01), respectively.

Included in net income and total comprehensive income for the nine-month period ended April 30, 2013 is a gain on sale from discontinued operations of \$6,014,000. On January 25, 2013, the Company announced the sale of its distribution business in Canada.

Excluding both the gain on sale and net income and total comprehensive income from discontinued operations, the Company recorded a net loss and total comprehensive loss from continuing operations of \$2,224,000 and \$6,281,000, respectively for the three and nine-month periods ended April 30, 2013 for a loss per common share of \$0.03 and \$0.09, respectively.

#### Research and development

Research and development costs totalled \$1,285,000 and \$4,266,000, respectively for the three and nine-month periods ended April 30, 2014. For the three and nine month periods ended April 30, 2013, research and development costs totalled \$1,303,000 and \$3,960,000, respectively.

L-DOS47 research and development expenses for the three and nine-month periods ended April 30, 2014 totaled \$794,000 and \$1,999,000, respectively (\$683,000 and \$2,092,000 respectively for the three and nine-month periods ended April 30, 2013). L-DOS47 research and development expenditures relate primarily to expenditures

associated with the ongoing European Phase I/II clinical study in Poland, costs associated with the preparation of the IND and CTA applications with the FDA and Health Canada, respectively and ongoing overhead costs in support of the L-DOS47 drug program.

Topical Interferon Alpha-2b research and development expenses for the three and nine-month periods ended April 30, 2014 totaled \$70,000 and \$308,000, respectively (\$87,000 and \$599,000 respectively for the three and nine-month periods ended April 30, 2013). Beginning in June 2012, the Company initiated a downsizing of the staff in the Saskatoon laboratory. The Company further downsized staffing levels at its Saskatoon laboratory in October 2012, including a decision that resulted in the closure of the Saskatoon laboratory at the end of November 2012. Costs associated with the downsizing were charged in fiscal 2013. The Company has now limited ongoing activities with respect to its Topical Interferon Alpha-2b program to sourcing and qualifying alternative interferon alpha-2b raw material samples, strengthening the Biphasix<sup>™</sup> patent portfolio and finding suitable strategic partner(s) who would be willing to license or acquire the product and support any remaining development costs.

Corporate research and development expenses for the three and nine-month periods ended April 30, 2014 totaled \$187,000 and \$1,213,000 respectively (\$339,000 and \$803,000 respectively for the three and nine-month periods ended April 30, 2013). Included in corporate research and development expenses for the nine-month period ended April 30, 2014 is a one-time payout of \$500,000 related to a severance payment.

Trademark and patent related expenses for the three and nine-month periods ended April 30, 2014 totaled \$142,000 and \$520,000, respectively (\$94,000 and \$118,000 respectively for the three and nine-month periods ended April 30, 2013). The Company has increased its efforts to strengthen the DOS47 and Biphasix™ patent portfolio.

#### Operating, general and administration

Operating, general and administration expenses for the three and nine-month periods ended April 30, 2014 totaled \$829,000 and \$2,666,000, respectively (\$911,000 and \$2,379,000 respectively for the three and nine-month periods ended April 30, 2013). Lower legal fees, consulting fees, travel and investor relations activities were the main drivers for lower operating, general and administration expenses for the three-month period ended April 30, 2014 when compared to the three-month period ended April 30, 2013, while on a year-to-date basis, these expenditures also reflect the higher spend in operating, general and administrative expenses.

In addition, during the quarter, the Company completed the wind-up and dissolution of Intercon Pharma Ltd., a wholly owned subsidiary in Ireland, which was undertaken to simplify the Company's corporate structure and repatriate cash.

## LIQUIDITY AND CAPITAL RESOURCES

The Company's cash reserves of \$2,832,000 as at April 30, 2014 are insufficient to meet anticipated cash needs for working capital and capital expenditures through the next twelve months, nor are they sufficient to see the current research and development initiates through to completion. To the extent that the Company does not believe it has sufficient liquidity to meet its current obligations, management considers securing additional funds, primarily through the issuance of equity securities of the Company, to be of the utmost importance.

The Company's condensed unaudited interim consolidated statement of financial position as at April 30, 2014 and July 31, 2013 are summarized below:

Consolidated Statement of Financial Posit	tion (thousand	<u>\$)</u>
	April 30 2014	July 31 2013
Non current assets	525	677
Current assets: Prepaid expenses Accounts receivable Cash	123 183 2,832 3,138	139 559 4,493 5,191
Total assets	3,663	5,868
Shareholders' equity	3,013	4,920
Current liabilities: Deferred lease credit Accrued liabilities Accounts payable	4 400 246 650	23 621 304 948
Total liabilities & shareholders equity	3,663	5,868

The Company's condensed unaudited interim consolidated statement of net loss and comprehensive loss for the three and nine-month periods ending April 30, 2014 and 2013 and the condensed unaudited interim consolidated statement of cash flows for the three and nine-month periods ending April 30, 2014 and 2013 are summarized below:

Consolidated Statements of Net Loss and Compre	henis	sve Loss						
(thousand \$, except for per share data)								
	For	For the three-month periods		For the nine-month periods			h periods	
		ended		ended				
		Apr-30		Apr-30		Apr-30		Apr-30
		2014		2013		2014		2013
Expenses:								
Research and development		1,285		1,303		4,266		3,960
Operating, general & administration		829		911		2,666		2,379
(Gain) on disposal of property, plant, equipment		-		-		-		(18)
Results from operating activities								
before finance items		(2,114)		(2,214)		(6,932)		(6,321)
Finance items		5		59		54		40
Loss and total comprehensive loss	_			-				
from continuing operations		(2,109)		(2,155)		(6,878)		(6,281)
Net income and total comprehensive income								
from discontinued operations		-		-		-		635
Gain from sale of discontinued operation		-		(69)		-		6,014
Net income (loss) and	_							
total comprehensive income (loss)	_	(2,109)		(2,224)		(6,878)		368
Loss per share from continuing operations *	\$	(0.03)	\$	(0.03)	\$	(0.10)	\$	(0.09)
Income per share from								
discontinued operations *	\$	-	\$	-	\$	-	\$	0.01
Total loss per common share *	\$	(0.03)	\$	(0.03)	\$	(0.10)	\$	0.01
* Figures are for both basic and fully diluted								

Consolidated Statements of Cash Flows (thousand	1\$)				
(thousand \$)	For the three-month periods ended		For the nine-month periods ended		
	Apr-30 2014	Apr-30 2013	Apr-30 2014	Apr-30 2013	
Cash provided by (used in):  Net loss and total comprehensive loss from continuing operations	(2,109)	(2,155)	(6,878)	(6,281)	
<u>.</u>	(2,100)	(2,100)	(0,070)	(0,201)	
Items not involving cash:	<b>5</b> 4	404	455	040	
Depreciation of property, plant and equipment  Deferred lease credit	51 (6)	104	155 (19)	310	
Stock-based compensation	118	(6) 68	299	(19) 240	
Foreign exchange loss	1	(51)	(34)	(24)	
(Gain) on disposal of property, plant, equipment	- '	-	-	(18)	
	(1,945)	(2,040)	(6,477)	(5,792)	
Changes in non-cash working capital	392	464	113	125	
Operating activities	(1,553)	(1,576)	(6,364)	(5,667)	
Financing activities	-	-	4,672	-	
Investing activities	-	(9)	(3)	(5)	
Effect of exchange rate changes on cash	(1)	51	34	24	
Net decrease in cash from continuing operations	(1,554)	(1,534)	(1,661)	(5,648)	
Net increase in cash from discontinued operations	-	(270)	-	7,460	
Cash beginning of the year	4,386	8,478	4,493	4,862	
Cash end of the year	2,832	6,674	2,832	6,674	

The Company's condensed unaudited interim consolidated financial statements and management's discussion and analysis are being filed under the Company's profile on SEDAR at <a href="www.sedar.com">www.sedar.com</a>, as well as on the Company's website at <a href="www.helixbiopharma.com">www.helixbiopharma.com</a>. Shareholders have the ability to receive a hard copy of the Company's unaudited condensed interim consolidated financial statements free of charge upon request at the address below.

## 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 currently listed on the TSX and FSE under the symbol "HBP".

#### **Investor Relations:**

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# Forward-Looking Statements and Risks and Uncertainties

This news release contains forward-looking statements and information (collectively, "forward-looking statements") within the meaning of applicable Canadian securities laws. Forward-looking statements are statements and information that are not historical facts but instead include financial projections and estimates, statements regarding plans, goals, objectives, intentions and expectations with respect to the Company's future business, operations, research and development, including the Company's activities relating to DOS47 and Topical Interferon Alpha-2b, including the sourcing and qualifying of alternative raw material samples, strengthening the BiPhasix™ patent portfolio and finding suitable strategic partners and other information in future periods.

Forward-looking statements include, without limitation, statements concerning (i) the Company's ability to operate on a going concern being dependent mainly on obtaining additional financing; (ii) the Company's priority continuing to be L-DOS47; (iii) the Company's development programs for Topical Interferon Alpha-2b, DOS47 and L-DOS47; (iv) the Company's European Phase I/II clinical trials for L-DOS47 in Poland including the number of cohorts required to reach MTD and the Company's potential protocol amendment in connection with this trial; (v) the Company's planned future U.S. Phase I clinical trial for L-DOS47 and the Company's CTA application in Canada; and (vi) future expenditures, the insufficiency of the Company's current cash resources and the need for financing and cost-cutting and/or cost-deferral measures and future financing requirements and the seeking of additional funding. Forward-looking statements can further be identified by the use of forward-looking terminology such as "2014", "ongoing", "estimates", "expects", or the negative thereof or any other variations thereon or comparable terminology referring to future events or results, or that events or conditions "will", "may", "could", "would", or "should" occur or be achieved, or comparable terminology referring to future events or results.

Forward-looking statements are statements about the future and are inherently uncertain, and are necessarily based upon a number of estimates and assumptions that are also uncertain. Although the Company believes that the expectations reflected in such forward-looking statements are reasonable, such statements involve risks and uncertainties, and undue reliance should not be placed on such statements. Forward-looking statements, including financial outlooks, are intended to provide information about management's current plans and expectations regarding future operations, including without limitation, future financing requirements, and may not be appropriate for other purposes. Certain material factors, estimates or assumptions have been applied in making forward-looking statements in this news release, including, but not limited to, the safety and efficacy of L-DOS47 and Topical Interferon Alpha-2b (low-grade cervical lesions); that sufficient financing will be obtained in a timely manner to allow the Company to continue operations; the Company's ability to commence the Phase I U.S. clinical trial for L-DOS47, the success of the Company's CTA application and the cost and timeline for reaching MTD in the Company's European Phase I/II clinical trial for L-DOS47 in Poland and/or that the Company's proposed protocol amendments for this study are accepted, in each case, on a timeline and on terms satisfactory to the Company; the timely provision of services and supplies, including Interferon Alpha-2b raw materials, or other performance of contracts by third parties; future costs; the absence of any material changes in business strategy or plans; and the timely receipt of required regulatory approvals and strategic partner support.

The Company's actual results could differ materially from those anticipated in the forward-looking statements contained in this news release as a result of numerous known and unknown risks and uncertainties, including without limitation, the risk that the Company's assumptions may prove to be incorrect; the risk that additional financing may not be obtainable in a timely manner, or at all, and that clinical trials may not commence or complete within anticipated timelines or the anticipated budget or may fail; third party suppliers of necessary services or of drug product and other materials may fail to perform or be unwilling or unable to supply the Company, which could cause delay or cancellation of the Company's research and development activities; necessary regulatory approvals may not be granted or may be withdrawn; the Company may not be able to secure necessary strategic partner support; general economic conditions, intellectual property and insurance risks; changes in business strategy or plans; and other risks and uncertainties referred to elsewhere in this news release, any of which could cause actual results to vary materially from current results or the Company's anticipated future results. Certain of these risks and uncertainties, and others affecting the Company, are more fully described in Helix's Annual Report, in particular under the headings "Forward-looking Statements" and "Risk Factors", and other reports filed under the Company's profile on SEDAR at www.sedar.com from time to time. Forward-looking statements and information are based on the beliefs, assumptions, opinions and expectations of Helix's management on the date of this new release, and the Company does not assume any obligation to update any forward-looking statement or information should those beliefs, assumptions, opinions or expectations, or other circumstances change, except as required by law.

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