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# HELIX BIOPHARMA CORP. ANNOUNCES FISCAL THIRD QUARTER 2021 RESULTS

(Richmond Hill, Ontario) – Helix BioPharma Corp. (TSX: "HBP"), a an immuno-oncology company developing drug candidates for the prevention and treatment of cancer, today announced its financial results for the fiscal third quarter ended April 30, 2021.

### **OVERVIEW**

The Company reported a net loss and total comprehensive loss of \$2,554,000 and \$5,268,000 for the three and nine-month periods ended April 30, 2021. For the three and nine-month periods ended April 30, 2020, net loss and total comprehensive loss totalled \$2,489,000 and \$6,896,000, respectively. The net loss and total comprehensive loss for the three-month period ending April 30, 2021, includes a net loss of \$nil (2020 - \$198,000) and for the nine-month period ending April 30, 2021 a gain of \$1,536,000 (2020 - loss of \$465,000) from discontinued operations. The Company lost control of its subsidiary in Poland during the three-month period ending October 31, 2020 though continued to exert significant influence until December 22, 2020 when the Company disposed of its remaining interest for gross proceeds of \$2,308,000.

# Clinical development

- Phase I combination therapy study in lung cancer (LDOS001):
  - Final clinical study report will be completed September 2021,
- Phase II combination therapy study in lung cancer (LDOS003):
  - The Company previously announced that it would not be advancing the randomized portion of this study without third-party partner funding. To date, no third-party partner has been identified.
- Phase Ib/II combination trial in pancreatic cancer (LDSOS006):
  - A second dose limiting toxicity ("DLT") has been reported in cohort 1 and as a result an additional three (3) patients are required per the approved protocol bringing the total number of patients required to complete cohort 1 to nine (9) patients,
  - In the event another DLT is observed in cohort 1, the Company will not be able to complete the currently planned dose escalation plan, but instead will be required to design a revision,
  - The Company continues to be committed to this study.
- ➤ L-DOS47 immunotherapy chemo combination study in lung cancer:
  - The Company is engaging key opinion leaders on the feasibility and design of this trial,
  - Depending on the outcome of these discussions and pending preclinical experiments, the Company plans to submit an Investigational New Drug application by December 2021.

## Corporate development

On May 13, 2021, the Company closed a \$3.5 million first tranche financing pursuant to a convertible security financing agreement with Lind Global Macro Fund LP. The convertible security has a two-year term and a

face value of \$4,112,500 and an aggregate of 1,957,056 common share purchase warrants exercisable into common shares in the capital of the company for a period of 48 months at an exercise price of \$1.0283 per common share. A \$6.5 million second tranche financing is also available to the Company provided both parties agree to close the second tranche.

- As a result of CAIAC Fund Management AG announcing control and direction over an aggregate of 26,363,172 Helix common shares, the Company no longer qualified under the Multijurisdictional Disclosure System ("MJDS") which accelerates cross border listings for Canadian companies. Without qualifying for MJDS, the Company requires financial statements to have been audited using U.S. Public Accounting Oversight Board ("PCAOB") auditing standards and in addition would require a PCAOB registered auditor in Poland to perform specific component audit procedures going back up to three years. As a result, the Company instead is prioritizing having its shares trade on the OTC Markets and for now, deferring a Nasdaq listing.
- The Company is also reviewing internal operations with the objective of streamlining and cutting costs.

## Research and development expenses

Research and development expense for the three and nine-month periods ended April 30, 2021 totalled \$1,933,000 and \$4,103,000, respectively (\$1,523,000 and \$4,601,000 respectively for the three and nine-month periods ended April 30, 2020).

Components of research and development expenses:

	For the three-month period ended April 30		For the nine-month period ended April 30	
	2021	2020	2021	2020
Research & development programs (excluding below) Salaries and benefits Stock-based compensation expense Amortization of property, plant and equipment Amortization of right of use assets Investment tax credits / government grants	\$ 1,540,000 399,000 13,000 3,000 36,000 2,000	\$ 1,164,000 337,000 9,000 13,000	\$ 2,965,000 953,000 24,000 37,000 94,000 30,000	\$ 3,585,000 886,000 89,000 39,000 — 2,000
-	\$ 1,933,000	\$ 1,523,000	\$ 4,103,000	\$ 4,601,000

The increase in research and development expenditures for the three-month period ended April 30, 2021, when compared to 2020 of \$410,000 mainly represents higher collaborative research spend of \$498,000 associated with ProMab CAR-T, slightly higher LDOS47 clinical program spend of \$75,000 and increased spend in intellectual property expenditures of \$31,000 which were offset by reductions in spend associated with contract manufacturing activity totalling \$252,000. The reduction in research and development expenditures for the nine-month period ended April 30, 2021, when compared to 2020 of \$498,000 represents higher collaborative research spend of \$503,000 associated with ProMab CAR-T and \$147,000 associated with the Moffit Cancer Centre relating to L-DOS47. The increase spend in collaborative research was more than offset by reductions in spend associated with the Company's LDOS47 clinical program totalling \$620,000, contract manufacturing activity totalling \$220,000 and intellectual property expenditures of \$303,000.

The Company has a sub-licensing agreement related to CAR-T with HIO, its former subsidiary, whereby the Company is responsible to fund only pre-clinical activity in exchange for future royalties and milestones. HIO would also be responsible for any intellectual property expenditures associated to the CAR-T program in the specific jurisdictions HIO has sub-licensed. The decrease in intellectual property amount expensed for the nine-month period ended April 30, 2021 when compared to 2020 includes an amount totalling \$174,000 which the Company has invoiced HIO and is showing as receivables at April 30, 2021.

Lower clinical operation expenses are due to spending having occurred in the prior year's quarters related to the Company's LDOS003 Phase II clinical study in Poland and the Ukraine which has since concluded but currently awaiting reporting which has been delayed due administrative disagreement as a result of overbilling by the clinical research organization overseeing the program. The Company's new LDOS006 Phase lb/II pancreatic clinical study in the U.S. was still in the early stages with U.S. FDA approval only having been received in August 2019 and

enrollment having commenced in December 2019. COVID19 had slowed down patient enrollment. The Company has recently added two new study sites in an effort to increase the rate of patient enrollment.

#### Operating, general and administration expenses

Operating, general and administration expenses for the three and nine-month periods ended April 30, 2021, totalled \$651,000 and \$2,772,000, respectively (\$862,000 and \$1,986,000 respectively for the three and nine-month periods ended April 30, 2020).

Components of operating, general and administration expenses:

	For the three-month periods ended April 301		For the nine-month periods ended April 30	
	2021	2020	2021 2020	
Operating, general and administration (excluding below	v) \$ 467,000	\$ 536,000	\$1,859,000 \$ 1,375,000	
Salaries and benefits	98,000	109,000	311,000 327,000	
Stock-based compensation	85,000	216,000	600,000 282,000	
Amortization of property, plant and equipment	1,000	1,000	2,000 2,000	
	\$ 651,000	\$ 862,000	\$2,772,000 \$ 1,986,000	

The decrease in operating, general and administration expenditures for the three-month period ended April 30, 2021 when compared to 2020 of \$211,000 mainly represents lower stock-based compensation expense associated with the vesting of stock options that were granted to directors of the Company over their vesting period of \$131,000 and lower investor relations expenses associated with the termination of both the ACM Alpha Consulting Management EST ("ACMest") and ACM Alpha Consulting Management AG ("ACMag") agreements on October 22, 2020 totalling \$139,000 which were partially offset by higher legal fees totalling \$73,000.

The increase in operating, general and administration expenditures for the nine-month period ended April 30, 2021 when compared to 2020 of \$786,000 mainly represents higher legal fees totalling \$433,000, stock-based compensation expense associated with the vesting of stock options that were granted to directors of the Company over their vesting period of \$366,000, audit fees of \$167,000, director fees of \$56,000, purchased analyst coverage spend of \$57,000 and business development spend of \$54,000. The increased spend was offset by lower investor relations mainly associated with the termination of both the ACMest and ACMag agreements totalling \$373,000.

### LIQUIDITY AND CAPITAL RESOURCES

The Company reported a net loss and total comprehensive loss of \$2,554,000 for the three-month period ended April 30, 2021 (2020 - \$2,489,000) and \$5,268,000 for the nine-month period ended April 30, 2021 (2020 - \$6,896,000). As at April 30, 2021 the Company had working capital of \$1,223,000, shareholders' equity of \$1,310,000 and a deficit of \$185,784,000. As at July 31, 2020 the Company had working capital of \$2,735,000, shareholders' equity of \$2,981,000, a deficit of \$180,516,000.

The Company experienced a working capital deficiency throughout fiscal 2018 and 2019 until August 21, 2019, when the Company closed the first of a series of private placements. In the nine-month period ending April 30, 2021, the Company completed two rounds of private placements for gross proceeds totalling \$4,100,000 and on December 22, 2020, the Company disposed of its remaining interest in a subsidiary for gross proceeds of \$2,308,000. On May 10, 2021, the Company entered into a definitive convertible security funding agreement and closed the first tranche under the Agreement on May 13, 2021, for gross proceeds of \$3,500,000. The Agreement also contemplates the issuance of a second Convertible Security upon the mutual agreement of the Company and the investor for gross proceeds to the Company of up to \$6,500,000.

The Company's cash reserves of \$2,266,000 as at April 30, 2021 are insufficient to meet anticipated cash needs for working capital and capital expenditures through the next twelve months, nor are they sufficient to see planned research and development initiatives through to completion. Though the funds raised have assisted the Company in dealing with its working capital deficiency, additional funds are required to advance the Company's clinical and preclinical programs and deal with working capital requirements. To the extent that the Company does not believe it has sufficient liquidity to meet its current obligations, management considers securing additional funds, to be critical for its development needs.

The Company's Interim Condensed Statement of Net Loss and Comprehensive Loss for the three and nine-month periods ending April 30, 2021 and 2020 are summarized below.

Interim Condensed Statements of Net Loss and Comprehensive Loss (unaudited)					
	Three-month periods ended		Nine-month periods ended		
	Apr-30-2021	Apr-30-2020	Apr-30-2021	Apr-30-2020	
Expenses:		_			
Research and development	1,933,000	1,523,000	4,103,000	4,601,000	
Operating, general & administration	651,000	862,000	2,772,000	1,986,000	
Results from operating activities before finance items	(2,584,000)	(2,385,000)	(6,875,000)	(6,587,000)	
Finance items	30,000	(11,000)	71,000	(8,000)	
Net loss from continuing operations	(2,554,000)	(2,396,000)	(6,804,000)	(6,595,000)	
Net gain (loss) from discontinued operations		(198,000)	1,536,000	(465,000)	
Net loss & total comprehensive loss	(2,554,000)	(2,594,000)	(5,268,000)	(7,060,000)	
Attributable to non-controlling interest	-	105,000	-	164,000	
Attributable to Helix BioPharma Corp	(2,554,000)	(2,489,000)	(5,268,000)	(6,896,000)	
Loss per share continuing operations	(\$0.02)	(\$0.02)	(\$0.05)	(\$0.05)	
Loss per share discontinued operations		-	\$0.01	-	
Loss per share - total	(\$0.02)	(\$0.02)	(\$0.04)	(\$0.05)	

The Company's Interim Condensed Statement of Financial Position as at April 30, 2021 and July 31, 2020 is summarized below.

Interim Condensed Statement of Financial Position (unaudited)				
	Apr-30-2021	Jul-31-2020		
Current assets:		_		
Cash	2,266,000	4,235,000		
Accounts receivable	392,000	180,000		
Prepaids	278,000	90,000		
Assets held for sale	-	155,000		
	2,936,000	4,660,000		
Non current assets				
Propert, plant and equipment	52,000	91,000		
Right of use assets	35,000	155,000		
	87,000	246,000		
Total assets	3,023,000	4,906,000		
Current liabilities:				
Accounts payable	1,265,000	1,416,000		
Accrued liabilities	414,000	301,000		
Lease liabilities	34,000	159,000		
Liabilities held for sale assets	-	49,000		
	1,713,000	1,925,000		
Shareholders' equity				
Attributable to Helix BioPharma Corp.	1,310,000	2,394,000		
Attributable to non-controlling interest		587,000		
	1,310,000	2,981,000		
Total liabilities & Shareholders' equity / (deficiency)	3,023,000	4,906,000		

The Company's Interim Condensed Financial Statements (unaudited) and Management's Discussion and Analysis will be filed under the Company's profile on SEDAR at <a href="https://www.sedar.com">www.sedar.com</a>, as well as on the Company's website.

# About Helix BioPharma Corp.

Helix BioPharma Corp. a clinical-stage biopharmaceutical company developing unique therapies in the field of immuno-oncology for the prevention and treatment of cancer based on the Company's proprietary technological platform DOS47. Helix is currently listed on the TSX 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 other information in future periods. Forward-looking statements can further be identified by the use of forward-looking terminology such as "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", 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; that sufficient financing will be obtained in a timely manner to allow the Company to continue operations and implement its clinical trials in the manner and on the timelines anticipated; the timely provision of services and supplies 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 the Company's annual management's discussion and analysis for the year ended July 31, 2020 under the heading "Risks and Uncertainties" and Helix's Annual Information Form, 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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