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December 22, 2020

John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com **10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606**

Helix BioPharma Corp. (HBP.TO - TSX)

Private Placement Completed

Based on our DCF model and a 15% discount rate, Helix is valued at approximately CAD$2.00 per share. Our model applies a 15% probability of ultimate approval and commercialization for L-DOS47 in NSCLC and pancreatic cancer. The model includes contributions from the United States and Europe.

Current Price (12/21/2020)	$0.31
Valuation ($CAD)	**$2.00**

OUTLOOK

Helix is an immuno-oncology company developing an anti-cancer therapeutic platform which acts by modulating the tumor micro-environment pH with an enzyme conjugated to an antibody. Helix's lead candidate, L-DOS47, is being evaluated in clinical trials for pancreatic cancer in combination with other agents. The antibody targets the CEACAM6 antigen in tumor cells allowing the linked urease enzyme to increase surrounding pH by catalyzing urea breakdown into basic ammonia. Additional DOS47 compounds are in the preclinical stage for solid tumors.

Lead candidate L-DOS47 is in Ph2 clinical trials for pancreatic cancer in combination with chemotherapy. We expect pivotal trials to generate registrational data in 2025 for both indications and work with a partner will advance the candidate outside North America.

Our valuation assumes a 2026 approval and launch of L-DOS47 in select markets including the US and Europe, the latter of which will be achieved through the efforts of partners.

SUMMARY DATA

52-Week High	**2.01**
52-Week Low	**0.25**
One-Year Return (%)	**-79.3**
Beta	**-0.04**
Average Daily Volume (sh)	**53,654**
Shares Outstanding (mil)	**135**
Market Capitalization ($mil)	**41.9**
Short Interest Ratio (days)	**0.04**
Institutional Ownership (%)	**19.8**
Insider Ownership (%)	**16.0**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2021 Estimate	**N/A**
P/E using 2022 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of CAD)

	Q1 (Oct)	Q2 (Jan)	Q3 (Apr)	Q4 (Jul)	Year (Jul)
2020	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2021	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2022					$0.0 E
2023					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2020	-$0.02 A	-$0.02 A	-$0.02 A	-$0.02 A	-$0.07 A
2021	$0.00 A	-$0.02 E	-$0.02 E	-$0.02 E	-$0.05 E
2022					-$0.08 E
2023					-$0.09 E

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WHAT'S NEW

First Quarter Fiscal Year 2021 Operational and Financial Results

Helix BioPharma Corp. (TSX: HBP.TO / OTC: HBPCF) reported first quarter fiscal year 2021 financial and operational results and submitted its SEDAR filings on December 15, 2020. During 1Q:21, extending from August 1 to October 31, 2020, Helix extended its collaboration agreement with Moffitt Cancer Center and executed a definitive agreement to divest Helix Immuno-Oncology (HIO). The LDOS006 Phase Ib/II clinical trial for metastatic pancreatic adenocarcinoma has dosed seven patients and one has presented a chemotherapy-related dose limiting toxicity, triggering the obligatory enrollment of three additional patients. Following the end of the quarter, Helix closed a private placement generating gross proceeds of $1.1 million.[1]

Operating expenses for the first quarter increased both sequentially and compared to the prior year and a gain related to the divestiture of HIO materially improved reported earnings. Financial results for the three months ended October 31, 2020 compared to the three months ended October 31, 2019 included:[2]

- Expenses for R&D were $1.1 million, down 25% from $1.4 million, the result of lower clinical operation expense, intellectual property maintenance cost and collaborative scientific research expenditure;
- Operating G&A expenses were $1.3 million, up 126% from $0.6 million, due to higher legal costs, investor relations expenditures and audit fees;
- Unique to 1Q:21 was a $2.2 million gain related to the loss of control over HIO;[3]
- Cash burn totaled ($2.8) million, improving from ($4.6) million.

As of October 31, 2020, cash stood at $1.4 million, compared to $4.2 million at the end of FY:20. Following the end of the quarter, additional cash related to the HIO divestiture and the private placement closed on December 7th was added to the balance sheet resulting in a cash balance of approximately $4.7 million as of mid-December.

The company continues with no debt on its balance sheet. Based on the cash balance and anticipated ~$2 to $3 million in quarterly cash burn, we anticipate a near term financing. Helix plans to list on the NASDAQ market next year and is in discussions with financers to conduct a capital raise for $15 to $20 million in conjunction with the new listing.

Polish Subsidiary

On June 26, 2020, Helix announced that it would be divesting its remaining ownership in its Polish subsidiary, Helix Immuno-Oncology S.A. (HIO). At the time of the announcement, Helix held a 51% interest in the entity following the sale earlier in the year of a 15.5% ownership stake. HIO had been developing V-DOS47, an antibody protein conjugate that targets vascular endothelial growth factor 2 receptor (VEGFR2) that is expressed in many carcinomas and lymphomas. Following the end of the reporting period, Helix cancelled approximately $2.7 million in intercompany debt owed to it by HIO. Assets related to Biphasix and V-DOS47 were transferred back to Helix. An increase in share capital was approved for HIO in early July, which allowed for 2.2 million shares to be issued raising gross proceeds of approximately 3 million Polish zloty. This action reduced Helix' interest in HIO to 42.5%. The company also accepted a non-binding offer to purchase the remaining interest for 6.7 million Polish zloty, equivalent to $2.3 million with CAIAC Fund Management AG. The transaction was originally scheduled to close on August 31, 2020 but was delayed due to coronavirus related issues. On November 9th, Helix announced that it had signed a definitive agreement to fully divest the subsidiary. Following closing requirements, Helix will recognize 5.9 million Polish zloty (~$2 million) after transaction costs.

Private Placement

On December 7, 2020, Helix announced the closing of a private placement with gross proceeds of $1.1 million. The terms of the placement were for the purchase of units at $0.50 per unit, each unit comprising one common share and one common share purchase warrant. Each common share purchase warrant will be exercisable at $0.70 with expiration in five years.

[1] Amounts are denominated in Canadian dollars unless otherwise stated.
[2] The comparative period for the period ending October 31, 2019 was adjusted in the most recent filing to reflect the divestiture of HIO and adjustments related to "Right of Use Asset" accounting
[3] The gain is not amounts related to the full divestiture of HIO, which occurred subsequent to the end of the first quarter.

Pipeline

The LDOS001 trial in the United States investigated L-DOS47 in combination with carboplatin and pemetrexed for non-small cell lung cancer (NSCLC). Topline data were presented at the American Society of Clinical Oncology (ASCO) conference this year. The clinical study report is now being developed and should be available in the first part of 2021. Below we provide a summary of the study results.

Exhibit I – LDOS001 Summary Presentation at ASCO[4]

LDOS001 Phase I Best Overall Response Summary Efficacy Evaluable(N=12)	
	L-DOS47 (All Dosing Cohorts) + Pemetrexed/Carboplatin
Best Overall Response	Overall
Number of Patients[1]	12
Complete Response (CR)	0 (0%)
Partial Response (PR)	5 (41.7%)
Stable Disease (SD)	4 (33.3%)
Progressive Disease (PD)	3 (25.0%)

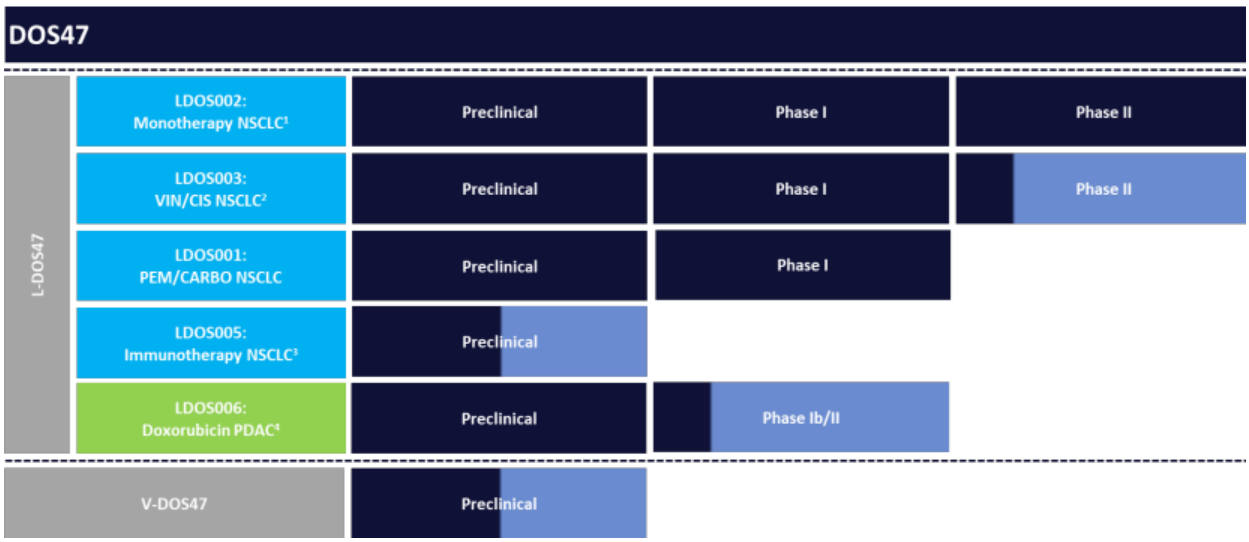
[1] Number of patients used as denominator to calculate percentages.

The LDOS003 trial investigating the benefit of L-DOS47 with a combination of vinorelbine and cisplatin for non-small cell lung cancer (NSCLC) patients has been completed, pending close out activities. This trial will not progress unless a partner is found. A report is being developed for the study that will likely be available in 2021.

Helix' pancreatic cancer trial, LDOS006, was launched in December 2019. As of December 2020, seven patients have been dosed, three of whom withdrew due to disease progression prior to completing the required 4-week cycle in order to be included in the evaluation for dose escalation. One patient experienced a chemotherapy-related dose limiting toxicity and as a result, three additional patients will need to be enrolled to close the first cohort. Due to slower enrolment related to challenges resulting from the pandemic, an additional two sites are engaged in study start-up activities, with plans to be open for patient recruitment in 1Q:21. A protocol amendment is also planned for submission to FDA in December 2020.

Most of the patients initially considered for the Phase Ib did not complete the safety cycle due to the late stage of their illness. Following enrollment in the Phase Ib portion, which is expected to complete in 2Q:21, Helix will progress to the 11-patient Phase II segment of the study. The Phase II portion of the study will focus on anti-tumor activity in the anticipated 11 patients. The subjects will be dosed with L-DOS47 in combination with 20 mg/m^2 doxorubicin with tumor marker measurements and radiological assessments every two treatment cycles.

Exhibit II – Product Development Pipeline[5]

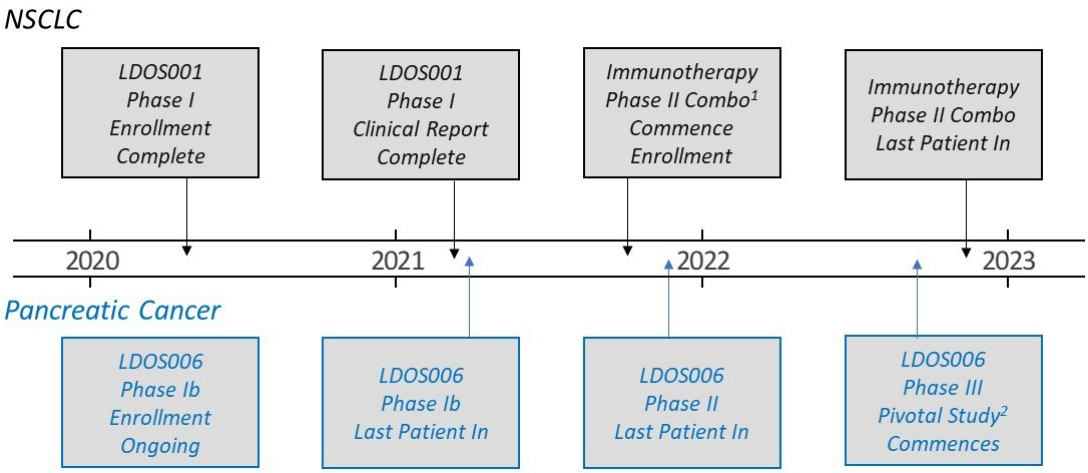


[4] Source: Helix Biopharma 1Q:21 SEDAR Filing, Management Discussion and Analysis.
[5] Source: Helix Biopharma August 2020 Corporate Presentation.

Corporate Milestones

- IND clearance by FDA for LDOS006 – August 2019
- Launch of LDOS006 study – December 2019
- Full divestiture of HIO – November 2020
- $1.1 million private placement – December 2020
- Availability of additional supply of L-DOS47 – Fall / Winter 2020
- Anticipated enrollment completion of LDOS006 Phase Ib –2Q:21
- LSDOS001 Phase I finalized clinical study report – April 2021
- Capital raise of $15 to $20 million and uplisting to NASDAQ – 2021
- LDOS006 Phase II last patient enrolled – 4Q:21
- Completion of LDOS003 clinical study report - 2021
- LDOS006 Phase III Launch – 2H:22

Exhibit III – Project Timing[6]



Summary

Helix has streamlined its operations with the successful divestiture of the HIO asset which generated cash that can be used to advance the LDOS006 trial. Helix also closed a $1.1 million private placement in December and continues talks with capital market firms targeting potential uplisting to the NASDAQ. With the additional capital and the two new sites planned for the LDOS006 trial, we see an acceleration in enrollment by 1H:21 and continued advancement of the pancreatic indication. The opportunity for L-DOS47 extends beyond the US and Europe and other programs in development provide additional opportunities to produce value. We maintain our price target of $2.00 per share.

[6] Source: Helix Biopharma 1Q:21 SEDAR Filing, Management Discussion and Analysis.

PROJECTED FINANCIALS

Helix BioPharma Corporation - Income Statement

Helix BioPharma Corp	2020 A	Q1 A	Q2 E	Q3 E	Q4 E	2021 E	2022 E	2023 E
Total Revenues ($CAD)	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
Research & Development	$5,868	$1,084	$1,575	$1,922	$2,229	$6,811	$10,000	$15,000
Operating, General & Admin	$2,748	$1,303	$520	$525	$530	$2,878	$3,500	$3,800
Income from operations	($8,616)	($2,387)	($2,095)	($2,447)	($2,759)	($9,689)	($13,500)	($18,800)
Other Income	$80	$7	$0	$0	$0	$7	$0	$0
Interest Expense	($25)	($4)	$0	$0	$0	$0	$0	$0
Pre-Tax Income	($8,985)	($222)	($2,095)	($2,447)	($2,759)	($7,520)	($13,500)	($18,800)
Provision for Income Tax	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	**($8,985)**	**($222)**	**($2,095)**	**($2,447)**	**($2,759)**	**($7,520)**	**($13,500)**	**($18,800)**
Net Margin								
Reported EPS	**($0.07)**	**($0.00)**	**($0.02)**	**($0.02)**	**($0.02)**	**($0.05)**	**($0.08)**	**($0.09)**
YOY Growth								
Basic Shares Outstanding	127,712	132,993	135,560	136,100	169,200	143,463	180,000	215,000

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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HISTORICAL STOCK PRICE

Helix BioPharma Corporation – Share Price Chart[7]



[7] Source: Zacks Research System

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