Zacks Small-Cap Research
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November 11, 2020
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Helix BioPharma Corp. (HBP.TO - TSX)

Polish Subsidiary Definitive Sale

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 (11/10/2020)	$0.30
Valuation ($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	**0.29**
One-Year Return (%)	**-73.4**
Beta	**-0.06**
Average Daily Volume (sh)	**21,334**
Shares Outstanding (mil)	**132.9**
Market Capitalization ($mil)	**39.9**
Short Interest Ratio (days)	**0.08**
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 2020 Estimate	**N/A**
P/E using 2021 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)
2019	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2020	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2021					$0.0 E
2022					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2019	-$0.01 A	-$0.02 A	-$0.02 A	-$0.02 A	-$0.07 A
2020	-$0.02 A	-$0.02 A	-$0.02 A	-$0.02 A	-$0.07 A
2021					-$0.07 E
2022					-$0.08 E

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WHAT'S NEW

Fiscal Year 2020 Operational and Financial Results

Helix BioPharma Corp. (TSX: HBP.TO / OTC: HBPCF) reported fiscal year 2020 financial and operational results and submitted its SEDAR filings on October 29, 2020. During the fiscal year, extending from August 1, 2019 to July 31, 2020, Helix launched its LDOS006 Phase Ib/II clinical trial in pancreatic cancer, executed a definitive agreement to divest Helix Immuno-Oncology (HIO), completed its LDOS003 Phase II program in non-small cell lung cancer and presented LDOS001 topline data. Other achievements over the last year include an extension of the agreement with Deloitte to expand partnering, discussions with several capital markets firms to raise funds to qualify for a NASDAQ listing and the raise of $12 million in capital.

Net loss for FY:20 was ($9.0) million,[1] which compares with the ($7.5) million loss in FY:19. On a per share basis, earnings were ($0.07). Research and development expense was $5.9 million, up 17% from prior year levels due to expenditure on manufacturing of L-DOS47 for use in clinical trials and expenditure for the Phase Ib/II pancreatic trial. These amounts were partially offset by a reduction in spend related to the L-DOS001 study, lower spending related to the research collaboration with the Moffitt Cancer Center and the wind down of the CAR-T program. General and administrative expenses were $2.7 million, rising 11% on increased expenditures for third party advisory services such as investor and media relations, legal, business development activities and investment banking services.

As of July 31, 2020, the cash balance was $4.2 million compared to $0.2 million at the end of the prior fiscal year. Cash burn for FY:20 was ($9.1) million, compared with prior year levels of ($5.5) million. During the fiscal year, Helix raised $13.1 million which will continue to fund operations and research and development activities. The company has no debt on its balance sheet. Based on the cash balance and anticipated ~$3 million in quarterly cash burn, we anticipate a cash raise in the near term. Helix plans to list on the NASDAQ market next year and is in discussions with bankers for a capital raise of $15 to $20 million in conjunction with the change in exchange.

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 CAD$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 should receive approximately 5.9 million Polish zloty (~CAD$2 million) after transaction costs and expects to receive the funds before the end of November.

[1] Share prices, value references in the text and financial statement items are denominated in Canadian dollars.

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. Below we provide a summary.

Exhibit I – LDOS001 Summary Presentation at ASCO

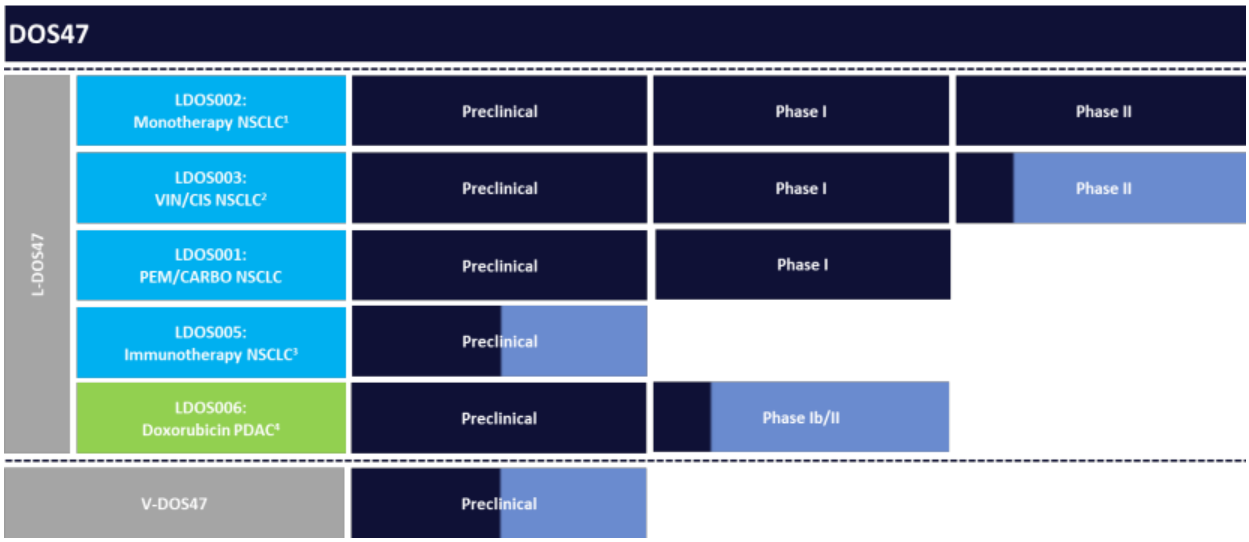
	L-DOS47 (All Dosing Cohorts) + Pemetrexed/Carboplatin
Best Overall Response	Overall
Number of Patients[1]	12
Complete Response (CR)	0 (0%)
Partial Response (PR)	5 (41.7%)
Stable Disease (SD)	4 (33.3%)
Progressive Disease (PD)	3 (25.0%)

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.

Helix' pancreatic cancer trial, LDOS006, was launched in December and has two patients that have completed the safety cycle in cohort 1 and one other patient undergoing the safety cycle. The study will use a 3x3 algorithm for dose escalation and is seeking two other sites to help accelerate its pace. It is combining chemotherapy agent doxorubicin with L-DOS47 in a dose escalating study for pancreatic cancer patients who have already undergone prior lines of therapy. Most of the patients that were initially considered for the Phase Ib did not complete the safety cycle due to the late stage of their illness. Following the enrollment in the Phase Ib portion, which is expected to complete in 2Q:21, Helix will immediately 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 L-DOS47 in combination with 20 mg/m^2 doxorubicin with tumor marker measurements and radiological assessments every two treatment cycles. Trial design details can be found at clinicaltrials.gov under identifier NCT04203641.

Exhibit II – Product Development Pipeline[2]



[2] Source: Helix Biopharma August 2020 Corporate Presentation.

Corporate Milestones

Below we list key milestones that have occurred in the last year and anticipated future events.

- IND clearance by FDA for LDOS006 – August 2019
- Launch of LDOS006 study – December 2019
- $6.0 million capital raise – March 2020
- LDOS001 ASCO presentation – 1Q:20
- LDOS002 clinical study report completed – June 2020
- Full divestiture of HIO – November 2020
- Availability of additional supply of L-DOS47 – Fall / Winter 2020
- Anticipated enrollment completion of LDOS006 Phase Ib –2Q:21
- Capital raise of CAD$15 to $20 million and uplisting to NASDAQ - 2021

Key reasons to own Helix shares:

- **Novel mechanism of action that is synergistic with other therapies**
- **CEACAM6 target is specific to tumor cells, especially lung and pancreatic adenocarcinoma**
- **Evidence that L-DOS47 may**
    - **Reverse acidic extra-cellular conditions favorable to cancer cell survival**
    - **Improve uptake of weak-base chemotherapeutics**
    - **Reduce PD-1 and PD-L1 expression thereby improving immune response**
- **L-DOS47 presents favorable drug safety profile with no reported drug-related adverse events**
- **Biologic eligible for 12 years of exclusivity in US and extended protection in other geographies**
- **North American rights to intellectual property**

Helix has streamlined its operations with the successful divestiture of the HIO asset and is expected to receive a net ~$2 million net in short order. The company is also planning a capital raise in the near term that will allow an 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 the company has other programs in development that may ultimately generate value. We maintain our current valuation opinion of $2.00 per share.

PROJECTED FINANCIALS

Helix BioPharma Corporation - Income Statement

Helix BioPharma Corp	2019 A	Q1 A	Q2 A	Q3 A	Q4 A	2020 A	2021 E	2022 E
Total Revenues ($CAD)	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
Research & Development	$5,006	$1,511	$1,588	$1,523	$1,600	$5,868	$8,000	$10,000
Operating, General & Admin	$2,486	$709	$654	$862	$750	$2,748	$3,000	$3,500
Income from operations	($7,492)	($2,220)	($2,242)	($2,385)	($2,350)	($8,616)	($11,000)	($13,500)
Other Income	($33)	$15	($10)	($211)	$0	$80	$0	$0
Interest Expense	($1)	($6)	($3)	$2	$0	($25)	$0	$0
Pre-Tax Income	($7,526)	($2,211)	($2,255)	($2,594)	($2,774)	($8,985)	($11,000)	($13,500)
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	**($7,526)**	**($2,211)**	**($2,255)**	**($2,594)**	**($2,774)**	**($8,985)**	**($11,000)**	**($13,500)**
Net Margin								
Reported EPS	**($0.07)**	**($0.02)**	**($0.02)**	**($0.02)**	**($0.02)**	**($0.07)**	**($0.07)**	**($0.08)**
YOY Growth								
Basic Shares Outstanding	106,646	121,818	125,526	130,636	132,869	127,712	150,000	180,000

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

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HISTORICAL STOCK PRICE

Helix BioPharma Corporation – Share Price Chart[3]



[3] Source: Zacks Research System

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