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Oncolytics Biotech Inc. (ONCYF - OTCQX)

SPA Is Green Flag for Phase 3 Pelareorep Trial

Based on our DCF model and a 15% discount rate, Oncolytics is valued at approximately $2.25 per share. Our model applies a 40% probability of approval for second line metastatic breast cancer based on interpolation of historical success ratios. Our valuation includes contributions from the US, EU and Japan.

Current Price (5/11/2018)	$0.63
Valuation	**$2.25**

OUTLOOK

Oncolytics is developing an oncolytic virus as a cancer therapy employing the reovirus in its clinical work. The company is currently focused on breast and pancreatic indications where its sole product, REOLYSIN, functions as an immuno-oncology agent.

The company's two key indications in breast (mBC) and pancreatic cancer use REOLYSIN in combination therapy. Based on the strength of its Ph2 data in mBC, REOLYSIN was granted fast track status and received an SPA from the FDA for its adaptive Ph3 trial to begin in 2018. The duration of the trial is expected to be ~3 years and it is targeted to enroll approximately 450 patients.

Interim analysis will be conducted by an IDMB at 200 events.

Assuming a 2022 launch of REOLYSIN, we believe the company's shares represent attractive value. Our target price of $2.25 per share is based solely on success in high mutation breast cancer.

SUMMARY DATA

52-Week High	**0.90**
52-Week Low	**0.32**
One-Year Return (%)	**0.0**
Beta	**0.59**
Average Daily Volume (sh)	**291,563**
Shares Outstanding (mil)	**142.4**
Market Capitalization ($mil)	**89.7**
Short Interest Ratio (days)	**2.67**
Institutional Ownership (%)	**1.0**
Insider Ownership (%)	**0.4**
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 2017 Estimate	**N/A**
P/E using 2018 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 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2018	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2019					$0.0 E
2020					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2017	-$0.03 A	-$0.03 A	-$0.02 A	-$0.03 A	-$0.12 A
2018	-$0.03 A	-$0.03 E	-$0.03 E	-$0.03 E	-$0.13 E
2019					-$0.16 E
2020					-$0.16 E

WHAT'S NEW

FDA Affirms SPA

Even though it has only been a few weeks since Oncolytics reported 2017 results, several new milestones have been achieved. The company announced participation at numerous conferences and programs including AACR and provided a review of the company's achievements over the last year at the annual meeting. The most important accomplishment realized was the FDA's agreement with the protocol design for Oncolytics' Phase III trial for REOLYSIN as described in the Special Protocol Assessment (SPA). This gives the company confidence to move forward with the study, which we expect to commence in the third quarter. Finally, Oncolytics received shareholder approval to perform a reverse split in order to qualify for a NASDAQ relisting.

On May 13th Oncolytics Biotech (OTCQX: ONCYF / TSE: ONC) announced 1Q:18 results along with their financial statements and MD&A. Net loss for the quarter was ($0.03) per share or ($4.6) million. No revenues were reported.

Research and development expenses were $2.9 million for 1Q:18. The line item increased 29% from the prior year levels on greater clinical trial, intellectual property, research collaboration and share based payment expenses. This was partially offset by slightly lower manufacturing expense and a foreign exchange adjustment. Operating expenses were up 36% compared to 2017 with office expenses (compensation costs) on higher headcount and share based payments driving the majority of the change.

Total expenses in the first quarter rose by 32% to $4.7 million and operating loss was ($4.7) million. The top three drivers for cost increases were clinical trial costs as Oncolytics prepared for the Phase III program, greater share based payments, and more employees. The company also maintained its office in San Diego, California, which did not exist in the same period last year. Due to rounding, loss per share remained at ($0.03) due to an increase in average shares outstanding from 121 million in 1Q:17 to 142 million in 1Q:18.

Cash stands at $7.7 million as of March 31, 2018 and operating burn was $4.7 million for the January to March period.

Looking Ahead to 2018 and 2019

The company has guided towards $16 million in cash burn for 2018 and expects higher levels in 2019 as the Phase III trial opens up full throttle. For 2018, our estimates call for an increase in R&D to $10.3 million and operating expenditures to $7.8 million, which represents a net loss of ($18.0) million. In 2019, we anticipate R&D to increase to $14 million and operating costs to expand to $10 million, yielding operating expenses of $24 million. We anticipate normal inflationary pressures over the remainder of the trial.

Based on guidelines provided by management, we estimate that the Phase III trial for HR+/HER2- metastatic breast cancer will cost from $70 to $80 thousand per patient and include 450 patients. The trial is expected to last approximately 3 years, which suggests approximately $1 million per month in direct trial related expenses. We also expect a small outlay for other work the company is doing in Phase II studies for other indications along with partners. We anticipate most of the costs related to these trials will be absorbed by academic institutions, grants and partners, which should limit the financial commitment largely to contribution of drug substance for these efforts.

Phase III Trial

Following discussions with the EMA and FDA, Oncolytics has developed an adaptive trial that is targeting 450 patients in a registrational trial in support of regulatory approval. This number of patients was increased from previous guidance of 400 patients due to additional biomarker work and inclusion of patients in Chinese sites that will be funded by partner Adlai Nortye. Patients will be HR+/HER2- and have failed one other prior chemotherapy treatment regimen in advanced metastatic breast cancer and must also have received treatment with a hormone based therapy that may or may not have included mTOR or CDK4/6 inhibitors. Patients will be randomized 1:1 on REOLYSIN and paclitaxel or paclitaxel monotherapy. There will be a maximum of eight 28-day treatment cycles of combination therapy in both the active and control arm. After the treatment period, patients will have the option to continue on with REOLYSIN monotherapy if deemed appropriate.

The primary endpoint for the study will be overall survival, with secondary endpoints of objective response rate, progression free survival and biomarker identification. The duration of the trial is expected to be from 36 to 48 months depending on the interim evaluation of the independent data monitoring board (IDMB).

The trial will target 150 sites in North America, Europe and some Asian countries which should allow for rapid enrollment. An interim analysis will be performed at 200 events (deaths) by an IDMB. As the trial is adaptive, the board will decide at that time if the trial needs to be extended from its target 36 month duration to 48 months. The interim analysis is expected to occur from 24 to 30 months following initial enrollment.

If the trial progresses as expected, then management expects to submit regulatory filings by 2022. The fast track designation granted REOLYSIN for this indication is expected to allow for close collaboration with the FDA, and potentially rolling review and accelerated approval which may speed REOLYSIN to market compared with the regular procedure.

Oncolytics received confirmation from the FDA on May 10 that its trial design was appropriate as described in the SPA. The SPA was submitted to the FDA in order to obtain additional input on trial design, clinical endpoints and statistical analyses that are acceptable to the agency. This is an important milestone which allows Oncolytics to proceed with confidence.

Other Studies

Oncolytics' primary goal is to further REOLYSIN in a Phase III trial for metastatic breast cancer. However, the company does have other indications that it is developing in conjunction with partners using combination therapies with checkpoint inhibitors, IMiDs and other compounds. These are targeting indications other than breast cancer including pancreatic cancer and liver cancer among others. Only minimal expense is expected from these trials as they are expected to be funded by partners and academic institutions. We believe these are important efforts, well worth the minimal effort and expense required as it provides a steady flow of data that can attract the attention of large pharmaceutical companies[1] and potentially show additional efficacy and safety for this promising biologic.

Oncolytics Seeking NASDAQ Listing

Oncolytics announced on January 29th that it will seek a listing on the NASDAQ exchange. A shareholder vote was held to approve the company's plans to consolidate shares and achieve the required listing price. The vote was in favor of the reverse split and the company is currently working through necessary details to effectuate the consolidation. The company remains in communication with the NASDAQ to determine the number of days above the pricing threshold required before the uplisting will be allowed and anticipates the move to NASDAQ will be a second quarter event.

As we discussed in an earlier report, the NASDAQ Capital Market[2] requires a minimum share price of $2.00 to commence listing on the exchange if market value of the listed security is greater than $50 million. While we do not know what the company is considering for the reverse split ratio, we see a 1:10 relationship as a reasonable choice as it makes the math a little easier and satisfies some of the other constraints that support additional institutional ownership and liquidity.

A NASDAQ listing brings an additional level of prestige to a company as well as a higher perceived level of quality due to the reporting and corporate governance requirements for the exchange. While Oncolytics is already meeting these standards, which are also required by the Toronto Stock Exchange (TSX), the reputational benefits are expected to increase volume of shares traded in the United States. Many institutional investors require their portfolio constituents to trade on the NASDAQ or NYSE due to the higher reporting standards and they also prefer shares to trade at a $5.00 or greater minimum price. While a reverse split and exchange uplisting will not change any of the fundamentals for the company, it will increase the pool of potential investors. This should result in better access to capital, greater liquidity and a tighter bid-ask spread.

[1] We highlight the transaction between Merck and Viralytics, where the latter was purchased by the former for ~$400 million to obtain their Phase II oncolytic virus Cavatak which is being examined in a number of cancers including melanoma, prostate, lung & bladder.
[2] https://listingcenter.nasdaq.com/assets/initialguide.pdf

Milestones

- Special Protocol Assessment
    - Submit to FDA in March 2018
    - Affirmative response received May 2018
- NASDAQ Uplisting - 2Q:18
- Initiate a Phase III registration study – 3Q:18
- Initiate partner-sponsored Phase II studies
    - Window of opportunity study in mBC – 2H:18
    - Basket study for biomarker and efficacy data – 2H:18
    - Combination study with pembrolizumab for pancreatic cancer - underway
- Raise additional funds prior to Phase III enrollment – FY:18
- MUK eleven first data readout - 2019

Summary

Oncolytics continued to have a busy schedule year to date with several posters presented and affirmation of the SPA by the FDA. These efforts have built the foundation for trial design development and the launch of the much-anticipated Phase III trial in 2018. Combined with these improvements and increased investor interest in the stock, Oncolytics will soon uplist to the NASDAQ, which we anticipate will increase liquidity and visibility for the company. These factors will be very helpful in supporting an additional capital raise anticipated prior to the start of the Phase III registrational trial for HR+/HER2- metastatic breast cancer. We maintain our target price to $2.25 per share and anticipate increasing the value further upon the launch of the Phase III trial as per our methodology.

PROJECTED FINANCIALS

Oncolytics Biotech, Inc. - Income Statement

Oncolytics Biotech Inc.	2017 A	Q1 A	Q2 E	Q3 E	Q4 E	2018 E	2019 E	2020 E
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
R&D	$9.4	$2.9	$2.4	$2.5	$2.5	$10.3	$14.0	$14.8
Operating	$6.2	$1.8	$2.0	$2.0	$2.0	$7.8	$10.0	$11.0
Other expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($15.6)	($4.7)	($4.4)	($4.5)	($4.5)	($18.1)	($24.0)	($25.8)
Operating Margin	-	-	-	-	-	-	-	-
Interest Expense	$0.1	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
Total Other Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($15.5)	($4.7)	($4.4)	($4.5)	($4.5)	($18.0)	($23.9)	($25.7)
Taxes & Other	($0.1)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($15.6)	($4.7)	($4.4)	($4.5)	($4.5)	($18.0)	($23.9)	($25.7)
Reported EPS	**($0.12)**	**($0.03)**	**($0.03)**	**($0.03)**	**($0.03)**	**($0.13)**	**($0.16)**	**($0.16)**
YOY Growth	-	-	-	-	-	-	-	-
Shares Outstanding	132.4	142.2	144.0	144.5	145.0	143.9	149.0	160.0

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

HISTORICAL STOCK PRICE

Oncolytics Biotech, Inc. –Price Chart

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