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ONC-TSX

Rating:	**Speculative BUY**
Target:	**$8.50**
Price:	$4.18
Return:	103%
Valuation:	NPV (40% disc), 20x EPS, 10x EV/EBITDA (F2025 estimates)

Market Data

Basic S/O (M)	42.3
FD S/O (M)	45.4
Market cap ($M, basic S/O)	137.3
Ent Val ($M, basic S/O)	110.5
Pro forma cash (rec Q, $M)	26.7
Tot. Debt (rec. Q, $M)	0.0
52 Week Range	$1.35-$7.84
Avg. Daily Volume (M)	0.9527
Fiscal Year End	Dec-31

Financial Metrics

In C$M	2022E	2023E	2024E
Breast cancer	0.0	0.0	17.1
Pancreatic cancer	0.0	0.0	0.0
Royalty rev, pelareorep	0.0	0.0	17.1
EBITDA ($M)	(23.6)	(22.4)	(4.3)
Net Inc ($M)	(24.1)	(22.9)	(4.8)
EPS (basic)	($0.57)	($0.54)	($0.11)
EPS (FD)	($0.53)	($0.50)	($0.11)
P/E	NA	NA	NA
EV/EBITDA	NA	NA	NA

Company Description

Oncolytics Biotech is an AB-based cancer biologics developer, with oncolytic reovirus formulation pelareorep/Reolysin undergoing testing in several Phae II cancer trials, mostly focused on breast & pancreatic cancer, and secondarily on multiple myeloma

Source: Consensus data- Refinitiv, Forecasts/Estimates - Leede Jones Gable

New Preclinical Data Further Supports Pelareorep's Utility in Combination Immuno-Oncology Therapy – Spec BUY

AB-based cancer biologics developer Oncolytics Biotech provided new preclinical data for its proprietary reovirus-based oncolytic virus formulation pelareorep. In a poster presented at an EU-based immune-oncology conference, Oncolytics showed that pelareorep could enhance the anti-cancer activity of simultaneously-deployed CAR-T (chimeric antigen receptor T-cell) based therapies in solid tumors, a tumor category that has not historically been amenable to CAR-T-based intervention.

New preclinical data builds on immunological themes for how pelareorep could exert anticancer activity when deployed in combination with other immune-based therapies. Oncolytics has published preclinical data on CAR-T-related themes before, and indeed, a few of the exhibits in the poster just presented were extracted from a 2020 paper in the journal *Nature Communications* for which Oncolytics shared authorship with collaborators at the Mayo Clinic and Duke University, as also in the updated study for which new pelareorep-relevant data were presented.

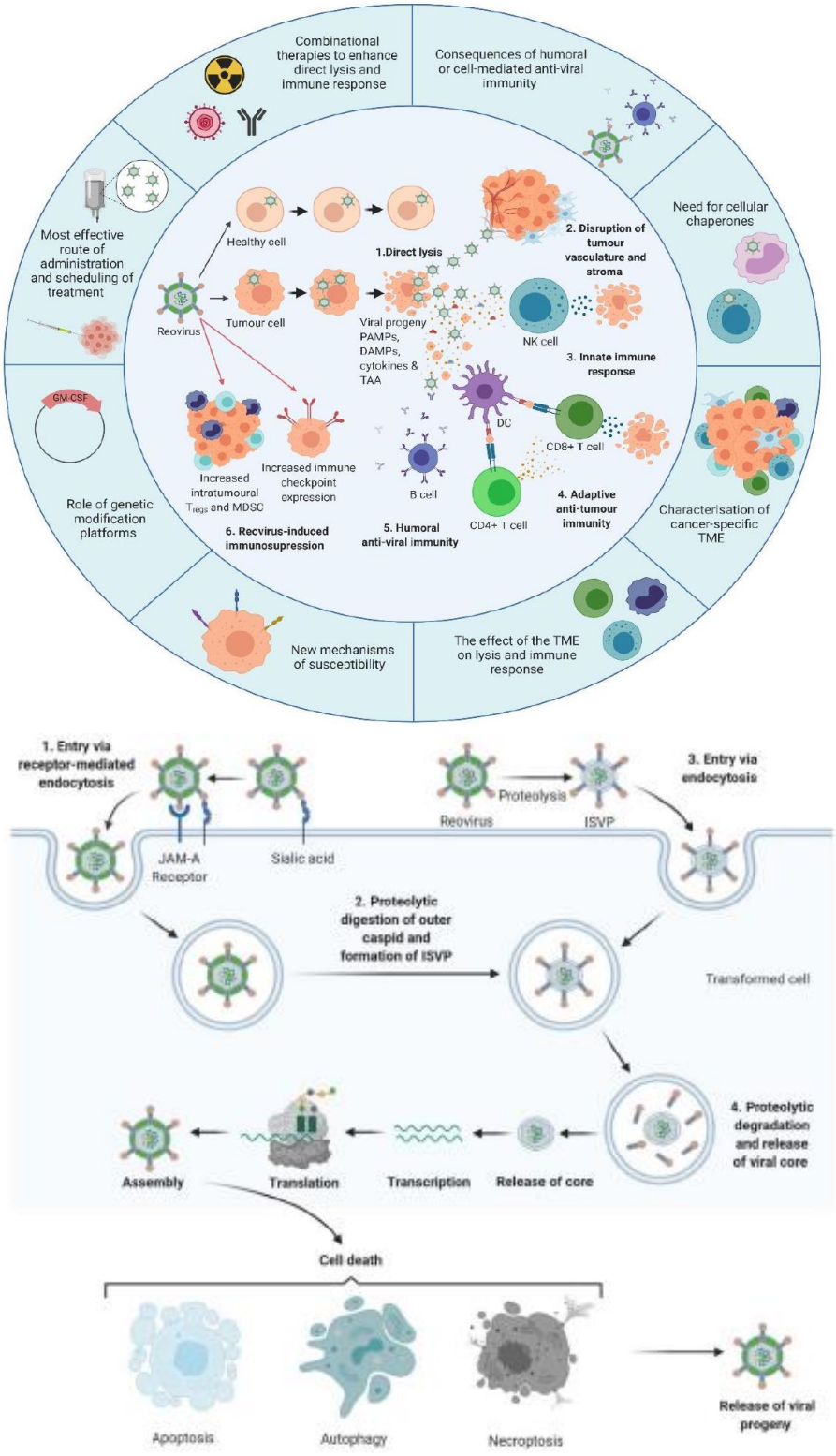
For context, in the aforementioned *Nature Communications* paper, Oncolytics and collaborators separately showed that a different oncolytic virus construct (one based on a different virus backbone called vesicular stomatitis virus, or VSV, and which was generically modified to express an immune cytokine called interferon-beta) could be co-administered with a CAR-T therapy. To be specific, pelareorep was pre-loaded into the antigen-directed CAR-T-cells beforehand to stimulate a T-cell immune response against target tumors in test animals. The target tumor was a B16 melanoma cell line that had been transfected with an altered form of the EGF receptor called EGFRVIII, a mutated receptor form that serves as the CAR target antigen as well), but with impact on tumor response or animal survival.

Oncolytics does not currently have any CAR-T/pelareorep combination therapies in formal clinical testing, but newly-published insights could motivate new clinical studies on the utility of this combination in solid tumors. The new study thus explored the possibility that pelareorep could alternatively be more effective at dampening immunosuppression that solid tumors can mount in response to CAR-T attack, and the results were encouraging. There is high medical interest in expanding cancer indications for which CAR-T-based therapies could be applied because their cumulative performance in pivotal Phase III leukemia/lymphoma trials was so strong. Several of which are already FDA-approved for targeting hematologic cancers but not solid tumors. These CAR-T-based therapies include Celgene/Kite's (now part of Bristol-Myers Squibb; BMY-NY, NR) axicabtagene ciloleucel/Yescarta, brexucabtagene autoleucel/Tecartus, or Novartis (NOVN-SW, NR)/ Juno's tisagenlecleucel/ Kymriah.

Our model is focused on pelareorep's clinical prospects in breast/pancreatic cancer, but new preclinical data even if in a melanoma/CAR-T model provides supplemental support for pelareorep's immune-based mechanism of action. As Oncolytics describes in its press release and in its poster linked therein, animals (mice) that harbored modified B16 melanoma tumors and were subsequently treated with pelareorep and a CAR-T therapy responded far better than did animals treated with

either pelareorep or CAR-T alone. Indeed, animal survival rate was essentially nil at forty day follow-up with pelareorep or CAR-T monotherapy, but 57% (four of seven) animals treated with both agents survived for >40 days, and those provided with a supplemental pelareorep infusion all survived beyond that time point.

Exhibit 1 – Many of the Proposed Mechanisms of Action for Pelareorep Relate to its Potential for Circumventing Local Immunosuppression in Solid Tumors, Thus Making Other Co-Administered Immunological Therapies More Active



Source: *Cancers* (2020). Vol. 12, pp. 3219-3245

Now, Oncolytics has long been a clinical-stage pelareorep developer and so new preclinical data however impressive does not overly move the needle on our valuation and investment thesis. Although B16 melanoma cells serve as a useful tumor model for testing CAR-T synergies, melanoma is not a clinical indication embedded into our model. Nonetheless, we are encouraged by all studies, even if preclinical, that support the mechanistic underpinnings for pelareorep and its utility when administered in combination with other immunologically-active agents, in this case CAR-T cell-based therapies. We would not be surprised if a Phase I solid tumor program testing pelareorep in combination with one or more of the aforementioned FDA-approved CAR-T platforms, modified to target breast/pancreatic cancer-relevant antigens and not B-cell antigens are they currently target, could be on the horizon in forthcoming quarters.

Exhibit 2 – Financial Summary for Oncolytics Biotech

(C$M, except per share data)	2019A	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Pelareorep royalty revenue, by indication										
Breast cancer	$0.0	$0.0	$0.0	$0.0	$0.0	$17.1	$78.4	$142.2	$203.9	$277.3
Pancreatic cancer	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$6.1	$24.5	$43.7	$63.6
Royalty rev, pelareorep	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$17.1**	**$84.5**	**$166.7**	**$247.6**	**$340.8**
Revenue growth (%)	*NA*	*NA*	*NA*	*NA*	*NA*	*NA*	*394%*	*97%*	*49%*	*38%*
Cash operating expenses	$18.7	$19.0	$22.5	$23.6	$22.4	$21.4	$20.6	$20.1	$22.3	$25.0
EBITDA	**($18.7)**	**($19.0)**	**($22.5)**	**($23.6)**	**($22.4)**	**($4.3)**	**$63.9**	**$146.6**	**$225.2**	**$315.9**
EBITDA growth (%)	*NA*	*NA*	*NA*	*NA*	*NA*	*NA*	*NA*	*229.4%*	*153.6%*	*140.3%*
EBITDA margin (%)	*NA*	*NA*	*NA*	*NA*	*NA*	*NA*	*75.6%*	*88.0%*	*91.0%*	*92.7%*
Net Income, fully-taxed	($20.7)	($19.5)	($23.0)	($24.1)	($22.9)	($4.8)	$44.3	$102.2	$157.2	$220.7
EPS (fully-taxed, basic)	**($0.64)**	**($0.46)**	**($0.54)**	**($0.57)**	**($0.54)**	**($0.11)**	**$1.05**	**$2.41**	**$3.71**	**$5.21**
EPS (fully-taxed, fd)	($0.57)	($0.43)	($0.51)	($0.53)	($0.50)	($0.11)	$0.97	$2.25	$3.46	$4.86
S/O (basic, M)	*32.2*	*42.3*	*42.3*	*42.3*	*42.3*	*42.3*	*42.3*	*42.3*	*42.3*	*42.3*
S/O (fully-diluted, M)	*36.1*	*45.4*	*45.4*	*45.4*	*45.4*	*45.4*	*45.4*	*45.4*	*45.4*	*45.4*
P/E	*NA*	*NA*	*NA*	*NA*	*NA*	*NA*	*3.3x*	*1.4x*	*0.9x*	*0.7x*
EV/EBITDA	*NA*	*NA*	*NA*	*NA*	*NA*	*NA*	*1.2x*	*0.5x*	*0.3x*	*0.2x*

Source: Historical data – Company Information (Oncolytics Biotech), Forecasts/Estimates – Leede Jones Gable

Multiple Phase I/II oncology trials could generate clinical pelareorep data during F2021/22, notably in metastatic breast cancer that is still the flagship indication in our model. On the milestone watch, we continue to closely monitor Oncolytics' metastatic breast cancer clinical program for which several Phase I/II clinical trials are either ongoing or are about to be. These include the 38-patient Phase II AWARE-1 trial, combining pelareorep with Roche's (ROG-SW, NR) anti-PD-L1 mAb Tecentriq. The trial is testing the combination for impact on early-stage breast cancer response rate/survival while identifying any relevant T-cell-based biomarkers that could predict pelareorep responsiveness both during and before therapy commences. Oncolytics is collaborating with the Spain-based clinical oncology organization SOLTI; final data form this trial are expected in FH121.

Secondly, we are tracking the 48-patient Phase II BRACELET-1 trial, testing pelareorep in combination with Pfizer's (PFE-NY, NR) anti-PD-L1 mAb avelumab/Bavencio. The trial commenced patient enrollment in FQ220 and we expect four-month response rate/survival/T-cell biomarker data to be available near end-of-F2021 (Exhibit 5). Both AWARE-1 and BRACELET are targeting patients with advanced metastatic breast cancers exhibiting a specific biomarker subtype (negative for the HER2 receptor, to which Herceptin would normally bind, but positive for either the progesterone or estrogen receptors). This is the disease subtype for which pelareorep/paclitaxel combination therapy was associated with highly-positive overall survival benefit as compared to paclitaxel monotherapy-treated patients, and those data still form the basis for much of our optimism on pelareorep's clinical prospects.

A third Phase II breast cancer trial being conducted in collaboration with Rutgers University researchers and alternatively targeting patients with triple-negative breast cancer (so none of the aforementioned HER2 or hormone receptors are expressed within this cancer form). The trial will explore pelareorep's anticancer activity when co-administered with Incyte's (INCY-Q, NR) development-stage anti-PD1 mAb retifanlimab. The 25-patient Phase II IRENE trial could generate two-month response rate/T-cell biomarker data by F2022, and then longer-term survival/PFS data in F2023. For now, our model does not contemplate pelareorep's utility in triple-negative breast cancer, though we will revisit that assumption if/when IRENE-derived survival data are available for our review.

At least three other Phase II cancer studies in pancreatic cancer and multiple myeloma could generate supplemental data this year as well. Shifting to pancreatic cancer, we continue to track progress on the firm's 30-patient Phase II advanced pancreatic cancer trial being conducted in collaboration with Northwestern University and combining pelareorep with Merck's (MRK-NY, NR) anti-PD1 mAb Keytrude; final survival/PFS data are expected later in FH121. And although our model does not formally ascribe value to multiple myeloma as a target indication, Oncolytics is surprisingly active in this realm with three ongoing or planned Phase II clinical studies focused on this cancer form.

These include a 28-patient NCI-partnered Phase II multiple myeloma trial testing pelareorep with Amgen's (AMGN-Q, NR) carfilzomib/Kyprolis, from which survival/T-cell biomarker data are expected later this year, and a separate 62-patient Phase II multiple myeloma trial testing pelareorep again with Kyprolis but also with Bristol Myers-Squibb's (BMY-NY, NR) anti-PD1 mAb nivolumab/Opdivo, from which interim survival data are expected by us near end-of-FH221 (OS/PFS data probably available in FH221). A third Phase II study, the still-pending 55-patient pancreatic/colorectal/anal cancer trial (GOBLET trial), will test pelareorep-Tecentriq combination therapy in these three solid-tumor indications. The trial is expected to start later this year, and perhaps generate interim survival/biomarker data by end-of-F2022.

Exhibit 3 – Valuation Scenarios for Oncolytics Biotech

NPV, discount rate		20%	30%	40%	45%	50%	60%
Implied value per share		$30.41	$15.68	**$8.29**	$6.21	$4.58	$2.46
				Discounted share price end-of-2021			
Price/earnings multiple, F2025	**P/E**	**20%**	**30%**	**40%**	**45%**	**50%**	**60%**
Implied share price[1]	10	$5.72	$4.50	$3.60	$3.24	$2.93	$2.41
	20	$11.44	$9.00	**$7.10**	$6.48	$5.86	$4.82
	30	$17.16	$13.50	$10.80	$9.72	$8.79	$7.23
EV/EBITDA multiple, F2025		**5x**	**7.5x**	**10x**	**12.5x**	**15x**	**20x**
Implied share price[1,2]		$5.44	$7.95	**$10.47**	$12.98	$15.49	$20.51
One-year ONC target price				$8.62			

[1] *Based on F2025 fd fully-taxed EPS forecast of $1.05; EBITDA of $63.9M; 40% discount rate*

[2] *EV incorporates FQ320 cash of $26.7M, no LT debt, S/O (fd) of 45.4M (42.3M basic S/O)*

Source: Forecasts/Estimates – Leede Jones Gable

Cash-contributing partnership with Chinese pharma firm Adlai Nortye is still in place (pelareorep is still in its pipeline) and we look for new clinical activities to advance in that geography in coming quarters. We have seen limited progress from Oncolytics' Asian partner Adlai Nortye (private) since the partnership was announced in F2017. But we remain encouraged that regional regulators in China have endorsed the firm's Phase III study design in metastatic breast cancer, and we are optimistic that this trial could begin imminently. Pelareorep is still prominently displayed in Adlai's R&D pipeline in its investor documents, but we are mindful that pelareorep's Phase III status was conferred back in 2019, and our model does not formally ascribe value to pelareorep sales in non-North American geographies as yet. As we described in our last note, Adlai did raise US$100M in new equity capital back in FQ320 and thus has sufficient capital to substantially drive pelareorep Phase III testing, even after considering capital requirements for what appears to be the firm's leae Phase III oncology asset, the PI3K inhibitor drug buparlisib (a 483-patient Phase III lung cancer trial, the BURAN trial, began in FQ320).

Summary and valuation. We are maintaining our Speculative BUY rating and one-year PT of $8.50 on ONC, with our valuation still based exclusively on pelareorep clinical milestones in the near-term and less on preclinical insights that are advanced in the background, however intriguing those insights might be. Our pelareorep royalty revenue projections are based on two specific cancer indications - HER2-negative/HR-positive breast cancer and advanced pancreatic cancer – as we show in Exhibit 2. Our model projects that Oncolytics could complete pivotal Phase III breast cancer testing and gain favorable FDA review by FH224, and then achieve similar milestones in pancreatic cancer by FH225. As we indicated in our initiation report last quarter, we do consider these timelines to reflect best-case scenarios and we anticipate revisiting our projected timelines to pelareorep commercialization when one or more pivotal oncology studies have formally commenced patient enrollment.

Exhibit 4 – Comparable Companies for Oncolytics Biotech

Company	Filing Curr	Sym	Shares Out (M)	Share price 23-Feb	Mkt cap ($M) (curr)	Mkt cap ($M) (C$)	Ent val ($M) (curr)	Ent val ($M) (C$)	Status of lead program
Bavarian Nordic AS	DKK	BAVA	58.4	DKK 225.0	DKK 13,143	2,710	DKK 14,243	2,937	Vaccine developer, focused on infectious disease but with HPV program with MVA-BN HPV in Phase II testing; BN-Brachyury/transcription factor vaccine in Phase II testing in advanced chordoma/bone cancer
Celldex Therapeutics	USD	CLDX	39.6	$28.25	1,118	1,410	918	1,158	CDX-0159, mAb targeting KIT tyrosine kinase (Phase I, angioedema); CEX-1140, mAb targeting CD40 (Phase II testing with Keytruda); CDX-527, bispecific mAb targeting PD-L1 & CD27 (Phase I, solid tumors)
Clovis Oncology	USD	CLVS	88.3	$6.68	590	744	963	1,214	Rucaparib developer (PARP inhibitor, ovarian cancer)
Dynavax Technologies	USD	DVAX	110.2	$9.60	1,058	1,334	1,060	1,337	Heplisav-B, recombinant hepatitis B vaccine; DNA vaccines targeting toll-like receptors (TLR7,8,9, as cancer therapies)
Incyte Corporation	USD	INCY	219.8	$79.92	17,570	22,156	15,803	19,928	Itacitinib (Phase III, chronic GvHD); Pemigatinib (Phase III, cholangio-sarcoma); INCMGA-00012 (Phase III, non-small cell lung cancer, anal cancer); ruxolitinib (myelofibrosis)
Iovance Bio-therapeutics	USD	IOVA	146.7	$43.00	6,308	7,954	5,593	7,053	Autologous T-cell immune therapies. C-144-01 (Phase II, melanoma); C-145-03 (Phase II, H&N cancer); C-145-04 (Phase II, cervical cancer)
Oxford Biomedica	GBP	OXB	82.4	p988.0	£814	1,444	£774	1,373	Lentivirus-based gene therapy (engineers T-cells to express Abs against 5T4 surface antigen) for multiple diseases, including hematologic cancers
Novavax, Inc.	USD	NVAX	63.7	$245.09	15,602	19,675	15,739	19,847	Nanoparticle vaccine technology, targeting viral respiratory pathogens
Oncorus	USD	ONCR	25.6	$18.51	474	598	594	749	Oncolytic virus developer; ONCR-177, intratumoral herpes virus construct in Phase I/solid tumor trial, coxsackievirus A21 (CVA21) in preclinical testing, IPO in Oct/20
Sunesis Pharma	USD	SNSS	18.1	$3.56	64	81	44	55	Vecabrutinib in Phase I B-cell lymphoma testing; PDK1 inhibitor SNS-510 in Phase I solid/hematologic tumor testing; Viracta merger is pending
Transgene	EUR	TNG	83.3	€ 2.45	€ 204	313	€ 178	273	Oncolytic vaccinia virus TG6002 in multiple cancer trials (breast cancer, mesothelioma; neoantigen vaccine TG4050 in Phase I H&N/ovarian cancer
VBI Vaccines	USD	VBIV	484.1	$3.52	1,704	2,149	1,600	2,017	Mostly focused on hepatitis B with Sci-B-Vac but also glioblastoma with VBI-1901 (bivalent VLP expressing the CMV Ags pp65 and gB)
Average						**$5,047**		**$4,828**	
Oncolytics Biotech	**CAD**	**ONC**	**43.3**	**$4.18**	**$181**	**$228**	**$155**	**$195**	**Reovirus-based pelareorep, Phase II testing in HER2(-)/ HR(+) breast cancer, pancreatic cancer, multiple myeloma**

Source: Refinitiv, Leede Jones Gable

With that caveat, our model still assumes as before that Oncolytics can generate positive royalty revenue from future partners by F2024, though with more substantive full-year royalty revenue expectations in F2025 of $84.5M, increasing to $166.7M in F2026 and $247.6M in F2027. Since our revenue model is royalty-based, it assumes that future marketing partners will incur all

manufacturing/marketing costs and so our EBITDA projections are quite close to our revenue projections (less modest administrative & constitutive R&D expenses) for that reason. Our model thus projects F2025 EBITDA of $63.9M, increasing to $146.6M in F2026 and $225.2M in F2027. As shown in Exhibits 2 and 3, F2025 is the reference year in our EBITDA/EPS-based valuation methodologies.

As with most of the clinical-risk firms in our coverage universe, we value ONC by using three distinct methodologies (Exhibit 3): NPV (40%), and multiples of our F2025 EBITDA/EPS forecasts ($63.9M/$1.05). Our discount rate of 40% is somewhat higher than we would normally ascribe to a Phase II/III-stage oncology drug developer, but we will review this valuation metric once Oncolytics formally advances pelareorep into pivotal studies. We use F2025 as the reference year in our EBITDA/EPS methodologies because it is the first full year during which we believe pelareorep could generate commercial sales for one or more oncology indications (assumed by us to be breast cancer or pancreatic cancer, or both).

Maintaining Spec BUY rating and $8.50 PT on ONC, with valuation still favorable as compared to acquired and publicly-traded peers. Taking the average of the aforementioned three methods gives us a one-year PT of $8.62, which we round to $8.50. On the milestone watch, we expect Oncolytics to provide interim data from several ongoing Phase I/II clinical studies in breast cancer and pancreatic cancer, and interestingly in multiple myeloma (Exhibit 5) to which our model does not ascribe formal value but which could be relevant to pelareorep's overall partnerability and revenue potential. Our PT corresponds to a one-year return of 103%.

We separately observe that Oncolytics' public market valuation is still at a steep discount to that ascribed to many of its oncolytic drug development peers, including but not limited to Herpes-based virus developer BioVex (acquired by Amgen (AMGN-Q, NR) for US$1B in FQ111), Australia-based coxsackievirus developer Viralytics (acquired by Merck (MRK-NY, NR) in FQ118 for US$394M), and vesicular stomatitis virus developer ViraTherapeutics (acquired by Boehringer Ingelheim for US$244M/€210M in FQ318 for what was at the time still a pre-Phase I-stage firm). We separately observe that MA-based oncolytic virus development peer Oncorus (ONCR-Q, NR), which just raised US$57M in new equity capital earlier this month and for which Phase I solid tumor testing for lead modified herpes virus-based ONCR-177 began in FQ320, is trading at current EV of US$594M. ONC is trading at an EV of C$195M.

Exhibit 5 – Forthcoming Clinical & Development Milestones for Pelareorep/Oncolytics Biotech

Expected milestone	Clinical trial	Cancer indication	Patient num (N)	Co-administered therapies	Clinical collaborators	Date (calendar)
Final biomarker (T-cell clonality, tumor infiltration) data	AWARE-1	Metastatic breast cancer (HER2-neg/ HR-pos)	38	Atezolizumab/ Tecentriq (anti-PD-L1 mAb)	Roche, SOLTI	Q121
Interim safety & biomarker data	BRACELET-1	Metastatic breast cancer	48	Avelumab/Bavencio (anti-PD-L1 mAb)	Pfizer & Merck KGaA	H121
Final survival-PFS-tumor response data	BU-18I01	Advanced pancreatic cancer (second-line)	30	Pembrolizumab/ Keytruda (anti-PD1 mAb)	Northwestern Univ, US NCI	H121
Interim safety & biomarker (T-cell clonality, tumor infiltration) data	IRENE	Triple-negative breast cancer (HER2-neg/ HR-neg)	25	Retifanlimab (anti-PD1 mAb)	Rutgers Univ, Incyte	H221
Commence enrollment (key biomarkers are T-cell clonality & CEACAM6 expression)	GOBLET	Advanced pancreatic, colorectal, anal cancer	55	Atezolizumab/ Tecentriq (anti-PD-L1 mAb)	Roche, AIO Studien gGmbH	Q221/Q321
Response rate, survival	WINSHIP 4398-18	Refractory multiple myeloma	62	Nivolumab/Opdivo or Carfilzomib/Kyprolis	BMS & Amgen	H121
Response rate, PFS, immune markers	NCI-9603	Refractory multiple myeloma	28	Carfilzomib/Kyprolis	Amgen	H221
Response rate & biomarker (T-cell clonality) data	BRACELET-1	Metastatic breast cancer	48	Avelumab/Bavencio (anti-PD-L1 mAb)	Pfizer & Merck KGaA	Q421/Q122

Source: Oncolytics Biotech, Leede Jones Gable

Disclosures none

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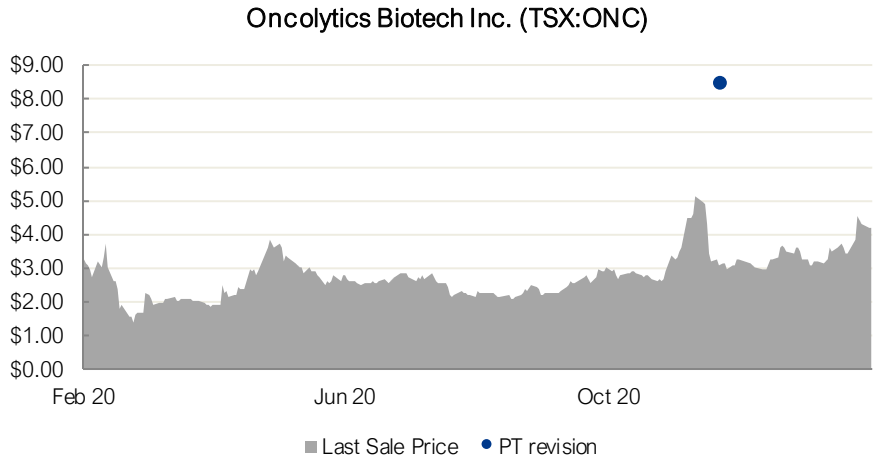
Rating Definitions

Buy	The security represents attractive relative value and is expected to appreciate significantly from the current price over the next 12 month time horizon.
Speculative Buy	The security is considered a BUY but carries an above-average level of risk.
Hold	The security represents fair value and no material appreciation is expected over the next 12 month time horizon.
Sell	The security represents poor value and is expected to depreciate over the next 12 month time horizon.
Under Review	The rating is temporarily placed under review until further information is disclosed.
Tender	Leede Jones Gable Inc. recommends that investors tender to an existing public offer for the securities in the absence of a superior competing offer.
Not Rated	Leede Jones Gable Inc. does not provide research coverage of the relevant issuer.

Rating Distribution

RECOMMENDATION	NO. OF COMPANIES	%
Buy	6	40.0%
Speculative Buy	8	53.3%
Hold	1	6.7%
Sell	-	-
Tender	-	-
Under Review	-	-

Historical Price Target



Date	Target ($)	Rating
15 Dec 2020	C$8.50	Spec Buy

Coverage Initiated: Dec 15, 2020

Data sourced from: Refinitiv