COMPANY NOTE

Company Update

USA | Healthcare | Biotechnology

May 21, 2015

Jefferies

EQUITY RESEARCH AMERICAS

Avalanche Biotechnologies (AAVL)

We Should Look At Eylea As A Proxy As Key Catalysts Approach In June/July

BUY

Price target $51.00

Price $39.05

Key Takeaway

We hosted investor meetings with AAVL management ahead of data from AVA-101, a gene therapy for wet age-related macular degeneration. The Phase IIa data is on track for a June/July readout and mgmt also plans to present long-term Phase I safety data which was previously anticipated in 2H w/ data at a medical mtg. On our analysis, we consider PIIa success as >4-5 letter imp't although a more modest imp't could support PIIb depending on inj frequency reductions.

Why We Should Look At Eylea As A Proxy? We believe Eylea serves as an important source of datapoints ahead of AVA-101 PIIa data b/c it's well-established as a potent anti-VEGF agent with sustained inhibition that enable less frequent administration (every 8 weeks) compared to Avastin/Lucentis (every 4-6 weeks), and there exists investigator reported data in patients that have switched from other anti-VEGF agents and may draw parallels to a similar patient pool in the current AVA-101 Phase IIa trial. A common misconception is treatment experienced patients behave the same as treatment naïve patients as evaluated with all PIIIs w/ marketed anti-VEGFs. We consider Phase II "home run" scenario where AVA-101 reports clinical relevant gains in VA compared to control (~4-5 letter improvement) w/ > 60% reduction in inj frequency, and a >100 um reduction in retina thickness vs baseline. We think AVA-101 could still move forward w/ a more modest VA benefit but a more pronounced inj freq reduction. Our analysis suggests the control arm should range btwn a 2 letter decline to a 1 letter gain at 12 months.

Review Of Refractory AMD Studies Suggests Anatomical Improvements Likely But VA Changes Unlikely. We analyze in our note several 12-month studies reporting Eylea administration in patients who are uncontrolled on Avastin/Lucentis. In each study, reductions in retina thickness ranged btwn 37-122 um compared to baseline. Visual acuity ranged from a 2 letter decline to a 1 letter gain vs baseline in 3 of 4 studies w/ one study reporting a 9-letter gain. We believe this Japanese study may provide critical read through into AVA-101 b/c Eylea was dosed in a consistent fashion over 12 mos albeit with healthier eyes than in AVA-101 Ph IIa. Also, baseline AVA-101 data suggest a third of pts have baseline VA of >70 letters, and these pts may drive VA gains vs ~20% of pts w/ poor vision.

Valuation/Risks

Our $51 PT is DCF-based. Risks include clinical, manufacturing, competitive, regulatory, and commercial.

Financial Summary	
Net Debt (MM):	($290.1)
Long-Term Debt (MM):	$0.0
Cash & ST Invest. (MM):	$290.1
Cash/Share:	$11.63
Cash (MM):	$290.1

Market Data	
52 Week Range:	$62.48 - $22.00
Total Entprs. Value (MM):	$350.3
Market Cap. (MM):	$640.4
Shares Out. (MM):	16.4
Float (MM):	19.0
Avg. Daily Vol.:	318,520

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USD	Prev.	2013A	Prev.	2014A	Prev.	2015E	Prev.	2016E
Rev. (MM)	--	0.5	--	0.6	--	0.8	--	0.0
EV/Rev		NM		NM		NM		
EPS								
Mar	--	--	--	(0.11)	--	(0.38)A	--	--
Jun	--	--	--	(2.27)	--	(0.40)	--	--
Sep	--	--	--	(0.50)	--	(0.43)	--	--
Dec	--	--	--	(0.46)	--	(0.46)	--	--
FY Dec	--	(1.45)	--	(2.46)	--	(1.68)	--	(1.89)
FY P/E		NM		NM		NM		NM

Price Performance

Review Of Refractory AMD Papers Reporting 12 Months Experience With Eylea: We searched for recent literature reports that reported 12 month efficacy experience of Eylea in AMD patients who were refractory to Avastin/Lucentis given the 12-month endpoint would be similar to AVA-101. However, we also would like to highlight the caveat that each of these were not randomized studies, nor were company sponsored data, and reported investigator experiences in patients that switched to Eylea from Avastin/Lucentis.

Arcinue CA and colleagues from UCSD (Am J Ophthal March 2015) conducted a retrospective analysis of 63 eyes in 58 patients with resistant neovascular age-related macular degeneration (AMD) were switched to bimonthly Eylea. The majority of the eyes had persistent subretinal fluid or intraretinal fluid with Avastin/Lucentis and had a median of 13 previous injections with Avastin/Lucentis (which compares comparably to AVA-101 Phase IIa median baseline of 10.5 previous injections). Patients were switched to Eylea every 8 weeks and if persistent fluid was observed then Eylea could be administered every 4 weeks. The baseline visual acuity was a logMAR of 0.40 or approximately 80 letters. Retinal thickness at baseline of 355 microns also is comparable to the Phase IIa patient baseline of a mean of 332.5 microns. Retinal thickness observed a mean 86 and 97 micron reduction at 6 months and 1 year, respectively. Visual acuity improved by 2.5 letters at 6 months but declined by 2 letters over baseline at year 1. At 12 months, 17 eyes (27%) were stable while 16 eyes gained (25.4%) and 28 eyes (44.4%) lost at least one line of ETDRS visual acuity. Patients in the analysis received a median of 4 Eylea injections with a third switching to every 4 weeks treatment.

Eadie and colleagues (Ophthalmic Surg Lasers Imaging Retina, Sept 2014) published a retrospective review of 111 patients at University of Wisconsin who had persistent exudation despite treatment with at least three injections of Avastin/Lucentis. The final analysis looked at 67 eyes in 63 patients who had been treated with Avastin/Lucentis for an average of 36.3 months and had received 3-38 prior injections, however, median nor mean numbers were reported. Patients received Eylea on average once every 6.5 weeks and received an average of 5.5 injections. Visual acuity reported no improvements in letters with baseline VA at approximately 75 letters (compared to 63 letters in AVA-101 Phase IIa). Center point retinal thickness decreased from 228.6 um to 176.9 um (p=0.001), and again in this subgroup these patients appear to have slightly healthier eye across visual acuity and retina thickness.

Grewal DS and colleagues (Eye, May 2014) did an interventional case series of 21 consecutive eyes in 21 neovascular AMD patients who were switched to Eylea with a baseline VA of 79 letters and central subfoveal thickness of 329 um. Patients had received 29.8 prior injections over 31.6 months on average. In the study, patients received Eylea according to the prescribing label w/ three monthly injections followed by every 8 week administration. At 6 months, visual acuity did not change compared to baseline and improved by 1 letter at 12 months. Central subfoveal thickness (CFT) decreased by 37 um at 1 year. Patients in the trial received a mean of 10.2 Eylea injections over 12 months, and this trial may be indicative of sustained anti-VEGF inhibition throughout the 12-month period.

We also reviewed a Japanese retrospective study (Nomura Y et al, Jpn J Ophthalmol, May 2015) in 16 wet AMD patients without choroidal vascular hyperpermeability (CVH) and reported a 9 letter improvement on a baseline VA of 84 letters. The mean number of Eylea injections was 9 injections over a 12-month period. Retina thickness decreased by 122 um on a baseline of 283 um at 12 months. The mean number of prior injections was 9 injections. Patients in this study appear to be healthier patients than in the AVA-101 Phase IIa study.

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In addition to these publications, we also reviewed data from short-term studies evaluating switching from Avastin/Lucentis to Eylea. Rishi and colleagues (Br J Ophthalmol, Mar 2014) reported on 26 patients who were switched after 14 mos of treatment. Patients had a baseline of 56 letters and retina thickness of 304 um and observed a 5.9 letter improvement at month 6. Data at year 1 has not been published yet. Retina thickness was reduced by 40 um.

A separate 6-month case report (Thorell MK et al, Ophth Surg Lasers Imaging Retina, Aug 2014) reported on 73 eyes who switched after a mean of 31 injections with baseline vision of 68 letters and a retina thickness of 257 um. Patients during the 6-month period received an average of 4.5 Eylea injections, and reported a 1.5 letter gain in visual acuity and a 19 um reduction in retina thickness.

AVA-101 Ph IIa Study Enrolled Primarily Treatment Refractory Patients. AAVL revealed key differences in the baseline characteristics b/w the Ph IIa and Ph I studies. Specifically, the Ph IIa trial enrolled 28 / 32 patients who were treatment-experienced (baseline average median of 10.5 inj in the Ph IIa vs 11.5 inj in the Ph I). Compared with the Ph I trial, patients in the Ph IIa study generally have better baseline vision (63 v. 36.5 letters), retinal thickness that is thinner (332.5 v. 549 microns), and a shorter duration of disease from diagnosis (16.2 mo v. 49.2 mo). We think VA would have the best odds of improvement in 11 of the 32 patients with baseline VA > 70 letters compared to the 6 of 32 patients with VA < 40 letters.

Valuation

We arrive at our $51 PT based on a DCF valuation model, which assumes a WACC of 14%, terminal growth rate of 0% and outstanding shares of 27.2 million, driven by sales of AVA-101. We assume market entry for AVA-101 for wet AMD in 2020 assuming positive data from a Phase III program. We estimate peak sales of $4.4 billion in the U.S. by 2026 for ophthalmic diseases including wet AMD, DME, and CRVO on an unadjusted-basis. If we apply a 65% risk discount to reflect the clinical risk of the AVA-101 program, we estimate $1.5 billion in U.S. sales by 2026. Additionally, we expect $118 million in royalty revenue for the same indications in 2026 using a 65% risk-discount.

At this time, we do not model AVA-201 for wAMD or AVA-311 for juvenile X-linked retinoschisis (XLRS), and these products represent upside. We estimate $135 million risk-adjusted peak sales for AVA-322/-323 for color blindness. We expect R&D expense to reach $26 million by YE 2015, increasing to $61 million by 2026 as AAVL ramps up clinical development of AVA-101 into DME and CRVO, AVA-201 and AVA-311. We expect SG&A expense to be $18 million by YE 2015, increasing to $58 million by 2026. We include $25 million in launch expenses for AVA-101 in 2021, risk-adjusted by 70%.

Exhibit 1: DCF sensitivity analysis

Discount rate	Equity Value	Price/Share
10.0%	$1,930.6	$71.77
12.0%	$1,618.5	$60.17
14.0%	**$1,367.1**	**$50.83**
16.0%	$1,163.6	$43.26
18.0%	$998.1	$37.11

Source: Jefferies estimates

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Risks

Clinical Failure: As with all companies in biotechnology and pharmaceuticals developing treatments of the future, a clinical failure can lead to delays in approval or possibly discontinuation of programs.

Regulatory Failure: The FDA could determine the Biologic Licensing Application is inadequate for AVA-101 for wet AMD and could delay approval. Furthermore, to date the FDA has not approved any gene therapy products for any indication. There is therefore no historical precedence for approval of such products, and the FDA may deem AAVL's clinical package for AVA-101 as insufficient for approval. Any delays in approval timelines could impact our earnings estimates, price target, and/or rating.

Commercial Failure: We currently estimate peak sales of $4.4 billion in the U.S. by 2026 for ophthalmic diseases including wet AMD, DME, and CRVO on an unadjusted-basis. If we apply a 65% risk discount to reflect the clinical risk of the AVA-101 program, we estimate $1.5 billion in U.S. sales by 2026. Additionally, we expect $117 million in royalty revenue for the same indications in 2026 using an 70% risk-discount. Our estimates may rely on the success of the company/partners to receive drug reimbursement from private/public payors.

Manufacturing Risks: AAVL relies on its proprietary baculovirus expression system (BVES) to produce its gene therapy products, including AVA-101. AAVL believes its BVES is efficient and scalable, with production yields up to 100x greater than those obtained by conventional AAV production system, allowing it to manufacture commercial grade production for large markets as wet AMD. If AVA-101 is approved, AAVL will need a consistent and reliable process, while limiting contamination risks, for manufacturing these candidates on large-scale for the approved patient population. Any supply or manufacturing disruption could negatively impact AVA-101 supply and sales.

Competitive Risks: Other companies are rapidly developing gene therapy product candidates in various stages of clinical development for ophthalmic diseases including wet AMD that may compete with AVA-101. If any of these product candidates have an improved therapeutic profile over AVA-101 and is approved, AVA-101's growth trajectory in the marketplace, even if approved, could be adversely impacted.

Financing Risks: We expect AAVL to have adequate cash through the majority of AVA-101's clinical development, and we model an $80 million equity raise on 2 million shares in 2019. AAVL may need additional dilutive financing to fund the potential U.S. launch of AVA-101 and its R&D programs in additional indications.

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Exhibit 2: AAVL Income Statement

Avalanche Biotechnologies, Inc.

Quarterly Income Statement

(All values in $MM except EPS and average shares)

	2012A	2013E	2014A	2015E					2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
	FY	FY	FY	1QA	2QE	3QE	4QE	FY	FY	FY	FY	FY	FY	FY	FY	FY
Revenue:																
AVA101- U.S.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	43.5	112.8	420.6	845.7
AVA101- ROW royalty	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	10.2	49.3	94.2
AVA322/323	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	50.0	75.0
License and collaboration revenues	0.0	0.5	0.6	0.2	0.2	0.2	0.2	0.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total revenue, net	**0.0**	**0.5**	**0.6**	**0.2**	**0.2**	**0.2**	**0.2**	**0.8**	**0.0**	**0.0**	**0.0**	**0.0**	**43.5**	**123.0**	**519.9**	**1,014.9**
Costs and expenses:																
Cost of goods sold	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	10.9	30.8	130.0	253.7
Research & development	13	2.2	17.0	5.6	6.2	6.8	7.5	26.1	31.3	36.0	39.6	43.6	45.7	48.0	50.4	52.9
Selling, general & administrative	0.5	1.8	8.0	4.1	4.4	4.6	4.8	17.9	19.6	21.6	23.8	25.0	26.2	45.0	47.3	49.6
Total operating expenses	**1.8**	**3.9**	**25.0**	**9.8**	**10.5**	**11.4**	**12.3**	**43.9**	**50.9**	**57.6**	**63.4**	**68.5**	**82.8**	**123.8**	**227.7**	**356.3**
Income (loss) from operations	**(1.8)**	**(3.5)**	**(24.4)**	**(9.6)**	**(10.3)**	**(11.2)**	**(12.1)**	**(43.1)**	**(50.9)**	**(57.6)**	**(63.4)**	**(68.5)**	**(39.3)**	**(0.8)**	**292.2**	**658.6**
Other income (expense):																
Miscellaneous (expense) income	(0.0)	(1.9)	(4.2)	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Interest income	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Interest expense	0.0	0.0	(0.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net profit (loss) before income taxes	**(1.8)**	**(5.3)**	**(28.6)**	**(9.5)**	**(10.3)**	**(11.2)**	**(12.1)**	**(43.1)**	**(50.9)**	**(57.6)**	**(63.4)**	**(68.5)**	**(39.3)**	**(0.8)**	**292.2**	**658.6**
Income tax expense (benefit)										0.0	0.0	0.0	0.0	0.0	29.2	230.5
Income tax (%)										*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*10.0%*	*35.0%*
Net Income (GAAP)	**(1.8)**	**(5.3)**	**(28.6)**	**(9.5)**	**(10.3)**	**(11.2)**	**(12.1)**	**(43.1)**	**(50.9)**	**(57.6)**	**(63.4)**	**(68.5)**	**(39.3)**	**(0.8)**	**15.0**	**428.1**
Adjusted Items (Non-GAAP)																
Stock options	0.0	0.0	0.0	0.6	0.7	0.8	0.9	3.0	4.0	5.0	6.0	7.0	14.0	16.0	18.0	20.0
Depreciation and amortization expense	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income (Non-GAAP)	**(1.8)**	**(5.3)**	**(28.6)**	**(8.9)**	**(9.6)**	**(10.4)**	**(11.2)**	**(40.1)**	**(46.9)**	**(52.6)**	**(57.4)**	**(61.5)**	**(25.3)**	**15.2**	**33.0**	**448.1**
EPS, GAAP																
Basic	(0.50)	(1.45)	(2.46)	(0.38)	(0.40)	(0.43)	(0.46)	(1.68)	(1.89)	(2.12)	(2.31)	(2.31)	(1.31)	(0.03)	0.49	13.84
Diluted	**$ (0.50)**	**$ (1.45)**	**$ (2.46)**	**$ (0.38)**	**$ (0.40)**	**$ (0.43)**	**$ (0.46)**	**$ (1.68)**	**$ (1.89)**	**$ (2.12)**	**$ (2.31)**	**$ (2.31)**	**$ (1.31)**	**$ (0.03)**	**$ 0.49**	**$ 13.84**
Weighted average share- Basic	3.6	3.7	11.7	24.9	25.6	25.9	26.1	25.6	26.9	27.2	27.4	29.7	30.0	30.3	30.6	30.9
Weighted average share- Diluted	3.6	3.7	11.7	24.9	25.6	25.9	26.1	25.6	26.9	27.2	27.4	29.7	30.0	30.3	30.6	30.9

Source: Jefferies, company data

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Exhibit 3: AAVL DCF analysis

Avalanche Biotechnologies

Discounted Cash Flow Analysis

(All values in $MM)	*2012A*	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Sales	*0.0*	0.5	0.6	0.8	0.0	0.0	0.0	0.0	43.5	123.0	519.9	1,014.9
Operating Expenses	*1.8*	3.9	25.0	43.9	50.9	57.6	63.4	68.5	82.8	123.8	227.7	356.3
EBIT	*(1.8)*	(3.5)	(24.4)	(43.1)	(50.9)	(57.6)	(63.4)	(68.5)	(39.3)	(0.8)	292.2	658.6
(-): Taxes	*0.0*	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	29.2	230.5
EBIAT	*(1.8)*	(3.5)	(24.4)	(43.1)	(50.9)	(57.6)	(63.4)	(68.5)	(39.3)	(0.8)	263.0	428.1
(+):Depreciation	*0.0*	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
(+):FAS-123 Options	*0.0*	0.0	0.0	3.0	4.0	5.0	6.0	7.0	14.0	16.0	18.0	20.0
(-): Capital expenditures	*0.0*	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Unlevered free cash flow	***(1.8)***	***(3.5)***	***(24.5)***	***(40.2)***	***(47.0)***	***(52.7)***	***(57.4)***	***(61.6)***	***(25.4)***	***15.2***	***280.9***	***448.0***

Source: Jefferies estimates, company data

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Company Description

Avalanche Biotechnologies, Inc., a clinical-stage biotechnology company, focuses on discovering and developing novel gene therapies for the treatment of ophthalmic diseases based on its Ocular BioFactory platform. Its lead product candidate includes AVA-101, which is in a Phase I/IIa trial for the treatment of wet age-related macular degeneration (AMD). The company is also developing AVA-201, an anti-vascular endothelial growth factor gene therapy product candidate for the prevention of wet AMD; and AVA-311 that is in preclinical studies for the treatment of juvenile X-linked retinoschisis, a rare genetic disease of the retina with no approved therapy. Avalanche Biotechnologies, Inc. has a collaboration agreement with Regeneron Pharmaceuticals, Inc. research, develop, and commercialize gene therapy products. The company was founded in 2006 and is headquartered in Menlo Park, California.

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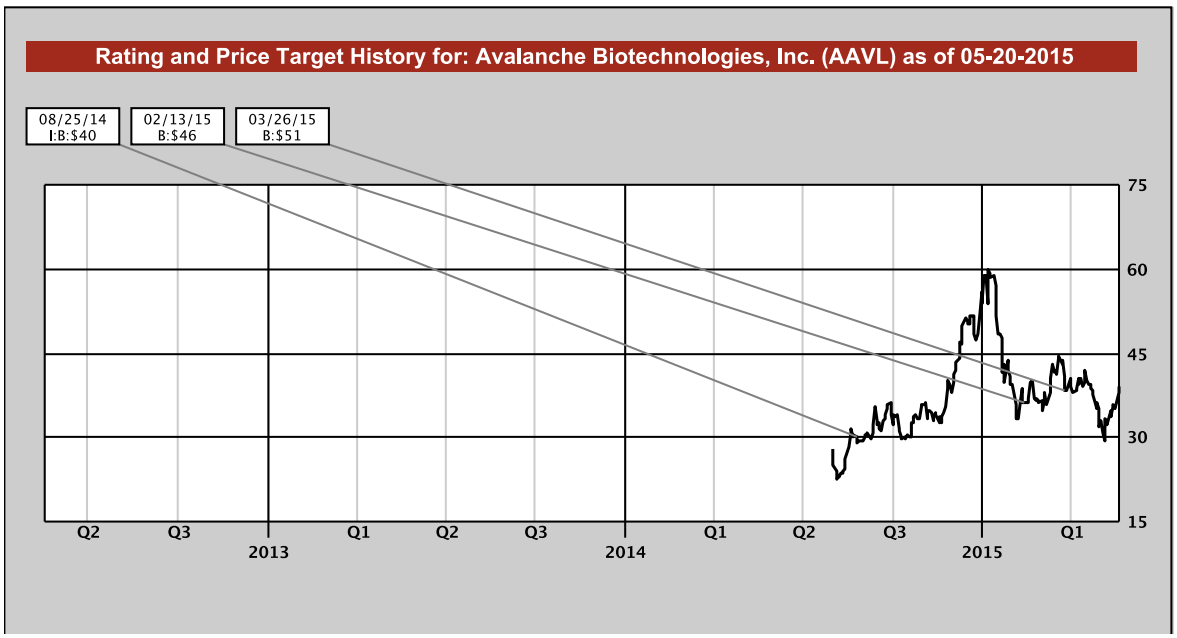
Other Companies Mentioned in This Report

- Avalanche Biotechnologies, Inc. (AAVL: $39.05, BUY)



Distribution of Ratings

Rating	Count	Percent	IB Serv./Past 12 Mos. Count	IB Serv./Past 12 Mos. Percent
BUY	1061	51.08%	289	27.24%
HOLD	845	40.68%	162	19.17%
UNDERPERFORM	171	8.23%	12	7.02%

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