COMPANY NOTE

Estimate Change

USA | Healthcare | Biotechnology

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Jefferies

EQUITY RESEARCH AMERICAS

Avalanche Biotechnologies (AAVL)

Q3 Update: Awaiting PIIa Data for AVA-101 In Wet AMD

BUY

Price target $40.00

Price $33.12

Key Takeaway

Q3 GAAP EPS loss was higher than expected on higher expenses. We continue to wait for topline data from the PIIa study for AVA-101 in mid-'15 for which we have a favorable outlook. A successful outcome would further validate AAVL's gene therapy platform. Further upside may come from 2 additional programs, AVA-201 for wAMD prevention and AVA-311 for XLRS, in preclinical development. We maintain Buy rating and $40 PT.

Awaiting Topline PIIa Trial Data for AVA-101 in Mid-'15: AAVL's lead candidate is AVA-101, a gene therapy which may offer durable remission for pts with wAMD. AVA-101 induces the retinal cells to produce sFlt-1, a naturally occurring VEGF inhibitor and clinically validated target. AVA-101 has shown impressive efficacy and safety results from 8 pts from its PI study. Mean VA improvement in the +12.2 and +9.8 letters for the low- and high-dose, respectively, v. control at wk 52. Impressively, fewer pts on AVA-101 required Lucentis re-tx relative to the control (0.33 v. 3.0, respectively) (p<0.001). Moreover, the effect appears durable lasting >12 mos. Given the Genzyme (a Sanofi company; SAN FP, €74.31, Hold) PI data for its intravitreally-delivered AAV2-sFlt01 product presented at Retina Society was underwhelming, AAVL may have the opportunity to differentiate. The PIIa trial has enrolled 32 pts, and we await topline data in mid-'15. AAVL also has potential to expand into DME and CRVO.

AVA-101 Role in Wet AMD: Anti-VEGF therapy dominates as the preferred tx of choice in wet AMD with current U.S. market size of ~$7-8B. AVA-101 could potentially displace regular anti-VEGF injections and could be preferred tx of choice in wAMD. We estimate AVA-101 may launch in 2020 and could generate a risk-adjusted $600M in peak U.S. sales (assuming 70% discount) in wAMD. Additional sales may also come from two add'l indications, CRVO and DME, which could generate $725M in risk-adjusted peak U.S. sales. Ex-U.S., we estimate peak risk-adjusted royalties of $120M, and do not include potential upfront payments/ milestones from an ex-U.S. partnership.

Q3 Financials: AAVL reported Q3 rev of $0.2M and GAAP EPS of ($0.50) [v. JEF est: ($0.14)] on higher expenses. Cash and equivs were $165.3M as of end-Q3 following the IPO proceeds of ~$106.5M in Aug.

Valuation/Risks

Our $40 PT is DCF-based. Risks include clinical, manufacturing, competitive, regulatory, and commercial.

Financial Summary	
Net Debt (MM):	**($165.3)**
Long-Term Debt (MM):	**$0.0**
Cash & ST Invest. (MM):	**$165.3**
Cash/Share:	**$10.10**
Cash (MM):	**$165.3**
Market Data	
52 Week Range:	**$37.38 - $22.00**
Total Entprs. Value (MM):	**$377.9**
Market Cap. (MM):	**$543.2**
Shares Out. (MM):	**16.4**
Float (MM):	**6.0**
Avg. Daily Vol.:	**120,813**

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USD	*Prev.*	**2013A**	*Prev.*	**2014E**	*Prev.*	**2015E**	*Prev.*	**2016E**
Rev. (MM)	--	0.5	*0.0*	0.4	--	2.0	--	0.0
EV/Rev		NM		NM		NM		
EPS								
Mar	--	--	--	(0.11)A	--	--	--	--
Jun	--	--	--	(2.27)A	--	--	--	--
Sep	--	--	*(0.14)*	(0.50)A	--	--	--	--
Dec	--	--	*(0.27)*	(0.33)	--	--	--	--
FY Dec	--	(1.45)	*(3.14)*	(3.55)	*(0.72)*	(0.87)	*(0.79)*	(0.94)
FY P/E		NM		NM		NM		NM

Price Performance

Valuation

We arrive at our $40 price target based on a DCF valuation model, which assumes a WACC of 14%, terminal growth rate of 0% and outstanding shares of 26.8 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 70% risk discount to reflect the clinical risk of the AVA-101 program, we estimate $1.3 billion in U.S. sales by 2026. Additionally, we expect $79 million in royalty revenue for the same indications in 2026 using a 70% risk-discount.

AAVL's initial target population for AVA-101 will be wAMD. We estimate peak sales of $2.0 billion in the U.S. by 2026 for wAMD on an unadjusted-basis. Applying a 70% risk discount to reflect the clinical risk of the AVA-101 program, we estimate $602 million in U.S. sales by 2026. AAVL intends to expand AVA-101 into CRVO and DME, and we assume market entry for these indications in 2022. For CRVO, we estimate peak U.S. sales of $510 million (unadjusted) and $153 million in 2026 (70% risk-discount). For DME, we estimate peak U.S. sales of $1.9 billion (unadjusted) and $573 million by 2025 (70% risk-discount).

For rest-of-world (ROW), we estimate peak sales of $783 million for wAMD by 2025 (unadjusted). We assume a 20% royalty for ROW sales and a 70% risk discount, translating to peak royalty revenue $47 million in 2025. For CRVO, we estimate peak ROW sales of $292 million in 2026 (unadjusted). Assuming a 20% royalty and 70% risk-discount, we estimate peak ROW sales of $18 million in 2026. For DME, we estimate peak ROW sales of $1.0 billion by 2025 (unadjusted). Under the same assumptions as wAMD and CRVO, we estimate peak ROW sales of $60 million in 2025 in DME.

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 expect R&D expense to reach $16 million by YE 2014, increasing to $53 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 $7.1 million by YE 2014, increasing to $42 million by 2026. We include $25 million in launch expenses for AVA-101 in 2021, risk-adjusted by 70%.

Exhibit 1: DCF sensitivity analysis

Equity Value	Price/Share
$1,515.0	$56.46
$1,263.2	$47.07
$1,060.0	**$39.50**
$895.4	$33.37
$761.4	$28.37

Source: Jefferies estimates

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

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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 70% risk discount to reflect the clinical risk of the AVA-101 program, we estimate $1.3 billion in U.S. sales by 2026. Additionally, we expect $79 million in royalty revenue for the same indications in 2026 using an 80% 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	2014E					2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
	FY	FY	1QA	2QA	3QA	4QE	FY	FY	FY	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	37.3	96.7	360.5	724.9	1129.3	1302.4
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	112.1	121.3
License and collaboration revenues	0.0	0.5	0.0	0.1	0.2	0.0	0.4	2.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total revenue, net	**0.0**	**0.5**	**0.0**	**0.1**	**0.2**	**0.0**	**0.4**	**2.0**	**0.0**	**0.0**	**0.0**	**0.0**	**37.3**	**106.9**	**409.8**	**819.0**	**1,241.4**	**1,423.7**
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	9.3	26.7	102.5	204.8	297.9	327.4
Research & development	13	2.2	0.9	3.1	5.7	6.3	16.1	18.0	18.0	40.0	42.0	44.1	45.9	47.2	48.7	49.6	50.6	51.6
Selling, general & administrative	0.5	18	0.7	1.5	2.4	2.5	7.1	7.3	7.4	7.6	7.7	7.9	8.0	34.0	35.7	37.5	39.0	40.5
Total operating expenses	**1.8**	**3.9**	**1.6**	**4.6**	**8.1**	**8.8**	**23.2**	**25.3**	**25.4**	**47.6**	**49.7**	**52.0**	**63.2**	**108.0**	**186.8**	**291.9**	**387.6**	**419.6**
Income (loss) from operations	**(1.8)**	**(3.5)**	**(1.6)**	**(4.5)**	**(7.9)**	**(8.8)**	**(22.8)**	**(23.3)**	**(25.4)**	**(47.6)**	**(49.7)**	**(52.0)**	**(25.9)**	**(1.1)**	**223.0**	**527.2**	**853.9**	**1,004.1**
Other income (expense):																		
Miscellaneous (expense) income	(0.0)	(1.9)	(0.0)	(3.9)	(0.3)	0.0	(4.2)	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	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	0.0	0.0
Net profit (loss) before income taxes	**(1.8)**	**(5.3)**	**(1.7)**	**(8.3)**	**(8.3)**	**(8.8)**	**(27.0)**	**(23.3)**	**(25.4)**	**(47.6)**	**(49.7)**	**(52.0)**	**(25.9)**	**(1.1)**	**223.0**	**527.2**	**853.9**	**1,004.1**
Income tax expense (benefit)										0.0	0.0	0.0	0.0	0.0	22.3	184.5	298.9	351.4
Income tax (%)										*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*10.0%*	*35.0%*	*35.0%*	*35.0%*
Net Income (GAAP)	**(1.8)**	**(5.3)**	**(1.7)**	**(8.3)**	**(8.3)**	**(8.8)**	**(27.0)**	**(23.3)**	**(25.4)**	**(47.6)**	**(49.7)**	**(52.0)**	**(25.9)**	**(1.1)**	**15.0**	**342.7**	**555.0**	**652.6**
Adjusted Items (Non-GAAP)																		
Stock options	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.0	4.0	5.0	6.0	7.0	14.0	16.0	18.0	20.0	22.0	24.0
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	0.0	0.0
Net Income (Non-GAAP)	**(1.8)**	**(5.3)**	**(1.7)**	**(8.3)**	**(8.3)**	**(8.8)**	**(27.0)**	**(20.3)**	**(21.4)**	**(42.6)**	**(43.7)**	**(45.0)**	**(11.9)**	**14.9**	**33.0**	**362.7**	**577.0**	**676.6**
EPS, GAAP																		
Basic	(0.50)	(1.45)	(0.45)	(2.27)	(0.50)	(0.33)	(3.55)	(0.87)	(0.94)	(1.74)	(1.80)	(1.74)	(0.86)	(0.03)	0.49	11.00	17.65	20.55
Diluted	**$ (0.50)**	**$ (1.45)**	**$ (0.45)**	**$ (2.27)**	**$ (0.50)**	**$ (0.33)**	**$ (3.55)**	**$ (0.87)**	**$ (0.94)**	**$ (1.74)**	**$ (1.80)**	**$ (1.74)**	**$ (0.86)**	**$ (0.03)**	**$ 0.49**	**$ 11.00**	**$ 17.65**	**$ 20.55**
Weighted average share- Basic	3.6	3.7	3.7	3.7	16.4	26.6	12.6	26.8	27.1	27.4	27.6	29.9	30.2	30.5	30.8	31.1	31.4	31.8
Weighted average share- Diluted	3.6	3.7	3.7	3.7	16.4	26.6	12.6	26.8	27.1	27.4	27.6	29.9	30.2	30.5	30.8	31.1	31.4	31.8

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	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Sales	*0.0*	0.5	0.4	2.0	0.0	0.0	0.0	0.0	37.3	106.9	409.8	819.0	1,241.4	1,423.7
Operating Expenses	*1.8*	3.9	23.2	25.3	25.4	47.6	49.7	52.0	63.2	108.0	186.8	291.9	387.6	419.6
EBIT	*(1.8)*	(3.5)	(22.8)	(23.3)	(25.4)	(47.6)	(49.7)	(52.0)	(25.9)	(1.1)	223.0	527.2	853.9	1,004.1
(-): Taxes	*0.0*	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	22.3	184.5	298.9	351.4
EBIAT	*(1.8)*	(3.5)	(22.8)	(23.3)	(25.4)	(47.6)	(49.7)	(52.0)	(25.9)	(1.1)	200.7	342.7	555.0	652.6
(+):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	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	22.0	24.0
(-): 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	0.0	0.0
Unlevered free cash flow	***(1.8)***	***(3.5)***	***(22.9)***	***(20.3)***	***(21.5)***	***(42.6)***	***(43.8)***	***(45.0)***	***(12.0)***	***14.9***	***218.6***	***362.6***	***577.0***	***676.6***

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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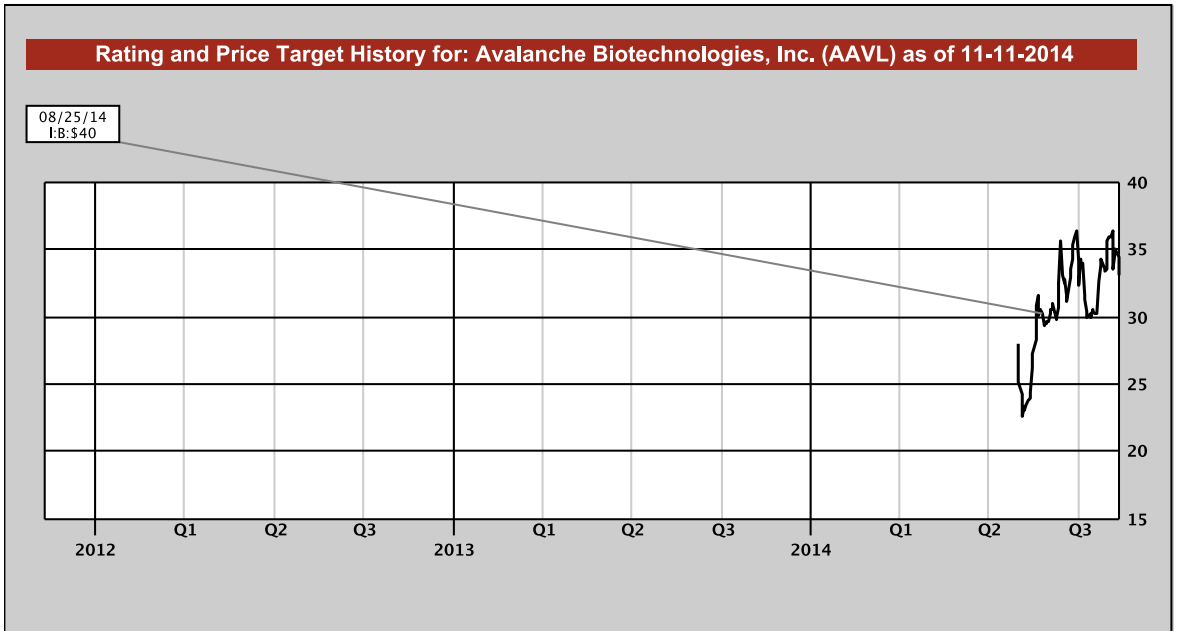
Other Companies Mentioned in This Report

- Sanofi (SAN FP: €74.31, HOLD)



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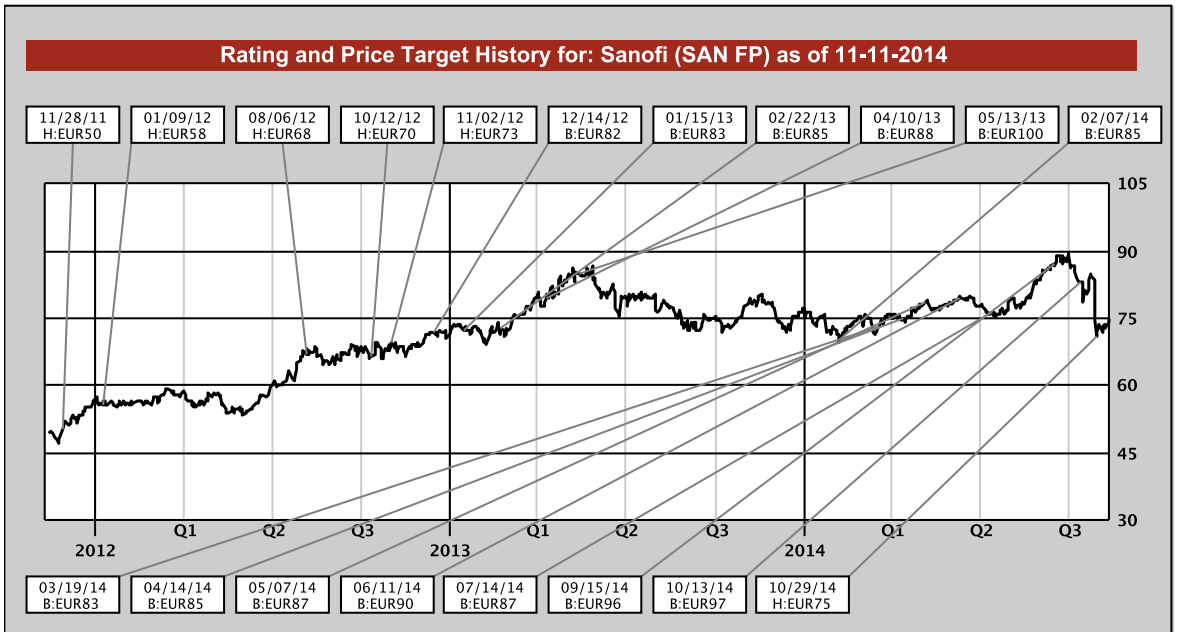

Distribution of Ratings

Rating	Count	Percent	IB Serv./Past 12 Mos. Count	IB Serv./Past 12 Mos. Percent
BUY	1019	52.04%	268	26.30%
HOLD	795	40.60%	142	17.86%
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