William Blair

Auspex Pharmaceuticals, Inc.

December 17, 2014

SD-809 Shows Robust Efficacy and Safety in FIRST-HD and ARC-HD Switch Trials, Raising Price Target to $70

- After the markets closed on Tuesday, December 16, Auspex Pharmaceuticals reported the top-line efficacy and safety readout of its pivotal Phase III study (FIRST-HD) and tetrabenazine-switch study (ARC-HD Switch) for its lead candidate, SD-809, for the indication of chorea associated with Huntington's disease. SD-809 has previously been granted orphan status by the FDA for the chorea associated with Huntington's disease indication.

- The results of both studies were significantly better than expectations with SD-809 meeting the primary endpoint of change in total mean chorea (TMC) score from baseline to maintenance therapy and several secondary endpoints in FIRST-HD, as well as showing safety and tolerability over four weeks in the ARC-HD Switch trial and a 0.8 reduction in TMC. As shown in exhibits 1 and 2, the primary endpoint of change in TMC score from baseline to maintenance therapy was a 4.4-point improvement from baseline to maintenance therapy versus a 1.9-point improvement in the placebo group in FIRST-HD. The trial also reported several positive secondary endpoints that were statistically significant, including the SF-36 physical functioning score (which is a quality of life measure) that management pointed out was not significant in the Phase III trial with Xenazine, the currently approved tetrabenazine product.

- FIRST-HD is a Phase III registration trial with a similar trial design to the Phase III trial for Xenazine (named TETRA-HD). Both FIRST-HD and TETRA-HD were run with the assistance of the Huntington Study Group. FIRST-HD was designed as a randomized, double-blind, placebo-controlled trial over a 12-week treatment period (N=90, 1:1 randomization, 45 patients in SD-809 and placebo groups) with a primary efficacy endpoint of TMC. Maximal chorea score is calculated by assessing chorea on seven different body parts (including face, mouth, trunk, and extremities) on a scale of 0 to 4 (0 = absent, 1 = slight/intermittent, 2 = mild/common or moderate/intermittent, 3 = moderate/common, 4 = marked/prolonged) for a potential score of up to 28. The baseline TMC score of patients in the FIRST-HD study was 12.7 whereas the baseline TMC score of patients in the TETRA-HD study was 14.9, which makes the results reported Tuesday by the company even more impressive because patients overall were presented with less severe chorea.

Auspex Pharmaceuticals is a leader in the development of deuterium-based therapies, with a focus on treatments for movement disorders. The company is based in San Diego.

Stock Rating:	**Outperform**
Company Profile:	**Aggressive Growth**
Price Target:	$70.00
Symbol:	ASPX (NASDAQ)
Price:	$25.09 (52-Wk.: $13-$36)
Market Value (mil.):	$692
Fiscal Year End:	December
Long-Term EPS Growth Rate:	
Dividend/Yield:	None

	2013A	2014E	2015E
Estimates			
EPS Q1	NA	A$-0.81	NA
Q2	NA	A$-0.45	NA
Q3	NA	A$-0.73	NA
Q4	NA	$-0.59	NA
FY	$-0.37	$-2.59	$-2.58
CY		$-2.59	$-2.58
Sales (mil.)	NA	0	0
Valuation			
FY P/E	NM	NM	NM
CY P/E		NM	NM

Trading Data (FactSet)	
Shares Outstanding (mil.)	26
Float (mil.)	7
Average Daily Volume	134,419

Financial Data (FactSet)	
Long-Term Debt/Total Capital (MRQ)	0.1
Book Value Per Share (MRQ)	5.2
Return on Equity (TTM)	-204.0

Two-Year Price Performance Chart

Sources: FactSet, William Blair & Company estimates

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- In parallel with FIRST-HD, the company completed ARC-HD Switch, a four-week trial that transitioned patients from stable doses of tetrabenazine after a one-week washout period onto lower daily doses of SD-809 (top-line results in Exhibit 3). At week one, the change for 36 patients was a decrease of 0.8 ± 0.4, and at week four, the change for 35 patients was a decrease of 0.8 ± 0.5. Additional ARC-HD analysis provided by the company at week eight of ARC-HD Switch showed a statistically significant decrease of 1.9 ± 0.8 in TMC, a result that exceeded expectations in a study that was meant to primarily show safety, tolerability, and non-inferiority when patients were switched from tetrabenazine to SD-809. In June, the company announced a prespecified interim subgroup analysis of the trial. At week one, patients showed a decrease in mean total chorea score of 0.83 (±0.51), while at week four, the patients assessed (N=8) mean total chorea scores had decreased by 0.75 (±0.75). The results showed Tuesday were consistent with the interim analysis, and went a step further in showing week eight data. The company noted that the data for the remaining 15 patients in the extension study will be available at a future date. Lastly, safety and tolerability in the ARC-HD Switch were consistent with the experience in the FIRST-HD Study.

- In exhibit 4, we show the reported adverse events in both FIRST-HD with SD-809 and TETRA-HD with Xenazine. We highlight several categories of adverse events where it is clear that SD-809 shows a significantly improved safety profile compared with Xenazine. It should be noted that the majority of diarrhea patients in the SD-809 trial were considered mild, and there were no differences in the serious adverse events from placebo in FIRST-HD. We believe that these results are a major proof-of-concept for the company as it looks to advance SD-809 in other movement disorder indications. Furthermore, this clean safety profile should lead to significant penetration of SD-809 into the current Huntington's disease patients treated with Xenazine as well as the HD patients with chorea who are not being treated with Xenazine due to the side effect profile of the therapy, which we believe is a significant patient population.

- As shown in exhibit 5, in addition to development of SD-809 in chorea associated with Huntington's disease, the company is currently enrolling AIM-TD (Addressing Involuntary Movements in Tardive Dyskinesia): a double-blind, placebo-controlled, parallel-group trial over a 12-week treatment period to enroll roughly 200 patients to assess SD-809 in the larger indication of tardive dyskinesia. Patients will be randomized 1:1:1:1 to receive three fixed doses of SD-809 or placebo. The company expects top-line data from the 18-month study by 2016 and a potential NDA submission by late 2016. The other Phase II/III study of SD-809 in tardive dyskinesia underway was initiated earlier this year and following discussions with the FDA, it will act as the first pivotal trial, pending positive results, which are due in mid-2015. Both the AIM-TD and the Phase II/III trials will feed into a one-year open-label safety study to collect long-term data necessary to support a regulatory filing. The primary efficacy endpoint in both studies is the change in the Abnormal Involuntary Movement Scale (AIMS) over 12 weeks. The company also plans to expand its ongoing Phase Ib open-label study for efficacy and safety of SD-809 to the treatment of tics associated with Tourette's syndrome to include adolescents and complete a pharmacokinetic study with another pipeline candidate, SD-560, versus pirfenidone for the indication of idiopathic pulmonary fibrosis (IPF) with top-line data for both studies expected by mid-2015.

- We continue Auspex Pharmaceuticals shares Outperform. We are increasing our price target from $42 to $70 due to stronger-than-expected safety and efficacy results from both the FIRST-HD and ARC-HD Switch trials. We have increased the penetration rates for SD-809 in chorea associated with Huntington's disease in both populations treated with Xenazine (as we believe it is a superior product) and populations that have not been treated with Xenazine (a subset of which is due to the adverse side effect profile of the compound). We are also increasing our clinical probability of success for chorea associated with Huntington's disease from 75% to 90%, and the clinical probability of success for SD-809 in tardive dyskinesia from 30% to 40% primarily due to the impressive side effect profile seen in both studies reported Tuesday. Following our placement of Auspex shares as a top fourth-quarter idea, given the strength of Tuesday's results, we continue to like the name into 2015 despite what will likely be significant appreciation of share price in the near term. We see several clinical and regulatory catalysts for shares during 2015 including a QT study readout in the first quarter, SD-809 for chorea NDA submission (with a potential decision on Priority Review), top-line data from SD-809 in tardive dyskinesia in the ARM-TD trial, early Tourette's disease data, and Phase Ib SD-560 readout in mid-2015.

Exhibit 1
First-HD Top-line Efficacy Results

Pre-Specified Motor Endpoints	SD-809	Placebo	Treatment Effect	Favors	p-value
Change in TMC Score from Baseline to Maintenance Therapy*	4.4 point improvement	1.9 point improvement	+2.5 points	SD-809	p<0.0001
Percent Change in TMC Score from baseline to Maintenance Therapy	37% improvement	16% improvement	+21%	SD-809	p<0.0001
Change in Total Motor Score (TMS) from Baseline to Maintenance Therapy	7.4 point improvement	3.4 point improvement	+4.0 points	SD-809	p = 0.002

Source: Company reports

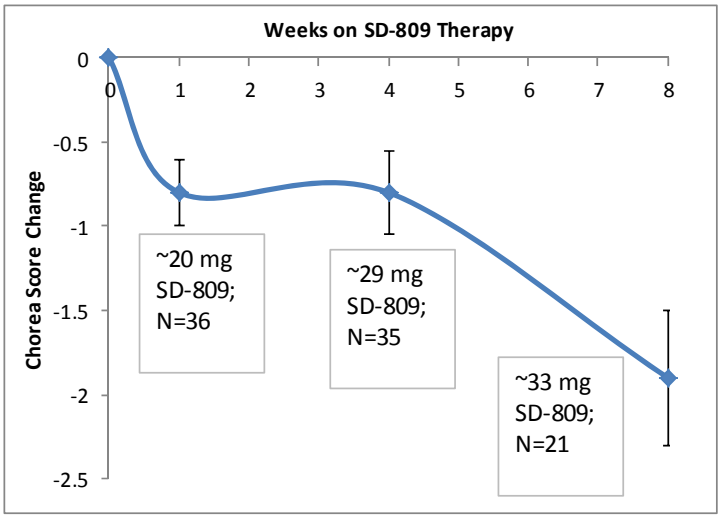
Exhibit 2
Auspex Pharmaceuticals
First-HD Key Secondary Endpoint Results

Pre-Specified Motor Endpoints	Favors	P-Value
Patient Global Impression of Change (PGIC)	SD-809	p = 0.002
Clinical Global Impression of Change (CGIC)	SD-809	p = 0.002
SF-36 Physical Functioning Score (a Quality of Life measure) from Baseline to Week 12**	SD-809	p = 0.03
Berg Balance Test	SD-809	p = 0.14

**Not significant in TETRA-HD study

Source: Company reports

Exhibit 3
Auspex Pharmaceuticals
ARC-HD Switch Efficacy Results



Source: Company reports

Exhibit 4. Adverse Event Profiles of Xenazine and SD-809 in Their Respective Pivotal Phase III Trials

Adverse Event Profile In Phase III with Xenazine (TETRA-HD) in Chorea Associated With Huntington's Disease

Body System	AE Term	Tetrabenazine N=30 n (%)	Placebo N=30 n (%)
Psychiatric Disorders	Sedation/somnolence	17 (31%)	1 (3%)
	Insomnia	12 (22%)	-
	Depression	10 (19%)	-
	Anxiety/anxiety aggravated	8 (15%)	1 (3%)
	Irritability	5 (9%)	1 (3%)
	Appetite decreased	2 (4%)	-
	Obsessive reaction	2 (4%)	-
Central & Peripheral Nervous System	Akathisia	10 (19%)	-
	Balance difficulty	5 (9%)	-
	Parkinsonism/bradykinesia	5 (9%)	-
	Dizziness	2 (4%)	-
	Dysarthia	2 (4%)	-
	Gait unsteady	2 (4%)	-
	Headache	2 (4%)	1 (3%)
Gastrointestinal System Disorders	Nausea	7 (13%)	2 (7%)
	Vomiting	3 (6%)	1 (3%)
Body as a whole - General	Fatigue	12 (22%)	4 (13%)
	Fall	8 (15%)	4 (13%)
	Laceration (head)	3 (6%)	-
	Ecchymosis	3 (6%)	-
Respiratory System Disoders	Upper respiratory tract infection	6 (11%)	2 (7%)
	Shortness of breath	2 (4%)	-
	Bronchitis	2 (4%)	-
Urinary System Disorders	Dysuria	2 (4%)	-

Source: Tetrabenazine label

Adverse Event Profile In Phase III with SD-809 (FIRST-HD) in Chorea Associated With Huntington's Disease

Body System	AE Term	SD-809 N=45 n (%)	Placebo N=45 n (%)
Psychiatric Disorders	Insomnia	3 (6.7%)	2 (4.4%)
	Depression/Agitated Depression	2 (4.4%)	3 (6.7%)
	Abnormal Dreams	1 (2.2%)	1 (2.2%)
	Agitation	1 (2.2%)	0 (0.0%)
	Anxiety	1 (2.2%)	1 (2.2%)
	Suicidal ideation	1 (2.2%)	0 (0.0%)
	Compulsions	0 (0.0%)	1 (2.2%)
	Impulsive Behavior	0 (0.0%)	1 (2.2%)
	Sleep Disorder	0 (0.0%)	3 (6.7%)
	Somnolence	5 (11.1%)	2 (4.4%)
Nervous System Disorders	Dizziness	2 (4.4%)	4 (2.2%)
	Akathisia/Restlessness	1 (2.2%)	1 (2.2%)
	Cognitive Disorder	1 (2.2%)	0 (0.0%)
	Drooling	1 (2.2%)	0 (0.0%)
	Dyskinesia	1 (2.2%)	0 (0.0%)
	Migraine	1 (2.2%)	0 (0.0%)
	Headache	0 (0.0%)	3 (6.7%)
	Loss of Consciousness	0 (0.0%)	1 (2.2%)
	Syncope	0 (0.0%)	1 (2.2%)
General Disorders	Irritability	3 (6.7%)	6 (13.3%)
	Fatigue	3 (6.7%)	2 (4.4%)
	Gait disturbance	1 (2.2%)	0 (0.0%)
	Chest pain	1 (2.2%)	0 (0.0%)
	Hangover	1 (2.2%)	0 (0.0%)
Gastrointestinal Disorders	Diarrhea	4 (8.9%)	0 (0.0%)
	Dry mouth	4 (8.9%)	3 (6.7%)
	Constipation	2 (4.4%)	1 (2.2%)
	Nausea	1 (2.2%)	2 (4.4%)
	Abdominal pain upper	1 (2.2%)	0 (0.0%)
	Dyspepsia	1 (2.2%)	0 (0.0%)
	Frequent bowel movements	1 (2.2%)	0 (0.0%)
	Gastrointestinal pain	1 (2.2%)	0 (0.0%)
	Vomiting	0 (0.0%)	3 (6.7%)
	Dysphagia	0 (0.0%)	1 (2.2%)
	Flatulence	0 (0.0%)	1 (2.2%)
	Salivary hypersecretion	0 (0.0%)	1 (2.2%)

Source: Auspex reports

Exhibit 5
Auspex Pharmaceuticals
Timeline of Development Programs for SD-809 and SD-560

Indication	Product	Update	Timing
Chorea Associated with Huntington's Disease	SD-809	Positive top-line data in FIRST-HD with primary endpoint and several secondary endpoints. ARC-HD Switch Study also met primary endpoint	NDA submission in mid-2015
Tardive Dyskinesia	SD-809	Phase II/III randomized placebo controlled trial study ongoing (first pivotal)	Phase II/III Top-line data expected in mid-2015
		Phase III trial initiated (second pivotal)	Phase III top-line data expected in 2016
Tics Associated with Tourette Syndrome	SD-809	Eight week efficacy and safety open-label Phase Ib, potentially expanded into adolescents	Top-line data expected in mid-2015
Idiopathic Pulmonary Fibrosis	SD-560	Evaluating Phase I pharmacokinetic clinical trial versus pirfenidone in healthy volunteers	Proof-of-Concept data expected in mid-2015

Sources: Company reports

Valuation

We rate Auspex Pharmaceuticals shares Outperform with a price target of $70. Our NPV is derived from a 90% probability of success applied to SD-809 for the indication of chorea associated with Huntington's disease (with peak sales of $539 million and approval in mid-2016) after the positive top-line readouts of both FIRST-HD and ARC-HD Switch trials as well as the clean safety profile over the currently approved product for this indication, Xenazine. In addition, we assign a 40% probability of success (with peak sales of $840 million) to SD-809 for the indication of tardive dyskinesia.

Auspex Pharmaceuticals
Risk Adjusted Sum of the Parts Valuation

Program	Peak Sales ($M)	Discount Rate	Probability of Success	Value	Value per share	% of NPV Value
SD-809						
Value for Huntington Disease	$539	9%	90%	$ 1,540,646	$ 50.51	72%
Value for Tardive Dyskenesia	$840	9%	40%	$ 651,349	$ 21.36	31%
Net Cash Per Share				$ 89,686	$ 2.94	4%
Debt				$ 13,387	$ 0.44	-1%
Discounted value of future net loss				$ (142,992)	$ (4.69)	-7%
Sum-of-the-parts NPV Valuation				$ 2,125,302	$ 69.68	100%

Source: William Blair & Company L.L.C. estimates

Risks

Given the stage of the company's pipeline, risks to an investment in Auspex shares are similar to other biopharmaceutical companies in the development phase. These risks primarily include clinical and regulatory setbacks, particularly in the lead indications for SD-809, chorea associated with Huntington's disease, and tardive dyskinesia.

William Blair

Rating: Outperform
Company Profile: Aggressive Growth

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Auspex Pharmaceuticals
Earnings Model
12/16/14
($ in thousands except EPS data)

	2012(A)	2013(A)	Q1(A)	Q2(A)	Q3(A)	Q4(E)	2014(E)	2015(E)	FY 2016(E)	FY 2017(E)
Product Revenue	-	-	0.0	0.0	0.0	0.0	-	-	74,540	272,369
Huntington's Disease	-	-	-	-	-	-	-	-	74,540	272,369
Tardive Dyskinesia	-	-	-	-	-	-	-	-	-	-
Tourette's Syndrome	-	-	-	-	-	-	-	-	-	-
Other Revenue		-	-	-	-	-	-	-	-	-
Total Revenue	-	-	-	-	-	-	-	-	74,540.0	272,368.8
yr/yr growth		NM	NA	NA	NA	NA	NA	NA	NA	265.4%
q/q growth			NA	NA	NA	NA				
incremental rev q/q										
Cost of Goods Sold	-	-	0	0	0	0	0	-	5,367	21,790
Gross Profit	-	-	0	0	0	0	0	0	69173	250,579
SG&A	1,688	3,189	2,674	2,908	3,107	3,500	12,189	18,200	22,750	34,125
Growth							20%	49%	25%	50%
R&D	11,741	10,003	3,432	7,131	10,802	12,000	33,365	48,000	50,000	57,500
Growth		0%					234%	44%	4%	15%
		-	-	-	-	-	-	-		
Total Operating Expenses	13,429	13,192	6,106	10,039	13,909	15,500	45,554	66,200	72,750	91,625
			137%	261%	376%	177%	245%	45%	10%	26%
Gain on sales of assets	-									
Operating Income	(13,429)	(13,192.0)	(6,106)	(10,039)	(13,909)	(15,500)	(45,554.0)	(66,200.0)	1,790.0	158,954.3
growth y/y (%)			NA	NA	NA	NA	245%	45%	-103%	8780%
Other income	(1,683.0)	(2,437.0)	(4,017.0)	(346.0)	(5,116.0)	125.0	(9,354)	(2,000)	(2,000)	(2,000)
Income Before Taxes	(15,112.0)	(15,629)	(10,123.0)	(10,385.0)	(19,025.0)	(15,375.0)	(54,908)	(68,200)	(1,977)	156,954
Income Tax Provision	-	-	-	-	-	-	-	-	1,000	53,364
Effective Tax Rate	0%	0%	0.0%	0.0%	0.0%	0.0%	0%	0%	-51%	34%
Net Income (loss)	$ (15,112)	$ (15,629)	(10,123.0)	(10,385.0)	(19,038.0)	(15,375.0)	$ (54,907.9)	$ (68,199.9)	$ (2,976.8)	$ 103,589.8
Net loss per share (fully diluted)	$ (2.50)	$ (0.37)	$ (0.81)	$ (0.45)	$ (0.73)	$ (0.59)	$ (2.59)	$ (2.58)	$ (0.12)	$ 3.80
Basic and diluted weighted avg. shares of common out	5,364	42,112	12,476	22,853	26,032	26,132	21,873	26,382	26,782	27,282

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Key Ratios (GAAP unless noted)

Gross Margin	NM	NM	NM	NM	NM	NM	NM	NM	92.0%	92.0%
R&D (% Total Rev.)	NM	NM	NM	NM	NM	NM	NM	NM	67.1%	21.1%
SG&A (% Total Rev.)	NM	NM	NM	NM	NM	NM	NM	NM	30.5%	12.5%
Operating Margin	NM	NM	NM	NM	NM	NM	NM	NM	2.4%	58.4%
Net Income Margin	NM	NM	NM	NM	NM	NM	NM	Nm	-4.0%	38.0%
Revenue Growth										
Growth Yr/Yr	NM	NM	NM	NM	NM	NM	NM	NM	NM	265%
Growth Q/Q	NM		NM	NM	NM	NM				
SG&A Growth										
Growth Yr/Yr	NM	89%	204%	665%	521%	75%	282%	49%	25%	50%
Growth Q/Q	NM		34%	9%	7%	13%				
R&D Growth										
Growth Yr/Yr	NM	-15%	102%	197%	346%	233%	234%	44%	4%	15%
Growth Q/Q	NM		-5%	108%	51%	11%				

IMPORTANT DISCLOSURES

William Blair was a manager or co-manager of a public offering of equity securities for Auspex Pharmaceuticals, Inc. within the prior 12 months.

William Blair is a market maker in the security of Auspex Pharmaceuticals, Inc..

William Blair intends to seek investment banking compensation in the next three months from Auspex Pharmaceuticals, Inc.

Within the past 12 months William Blair has provided or is providing investment banking services to or has an investment services relationship with Auspex Pharmaceuticals, Inc.

Additional information is available upon request.

This report is available in electronic form to registered users via R*Docs™ at www.rdocs.com or www.williamblair.com.

Please contact us at +1 800 621 0687 or consult williamblair.com/Research-and-Insights/Equity-Research/Coverage.aspx for all disclosures.

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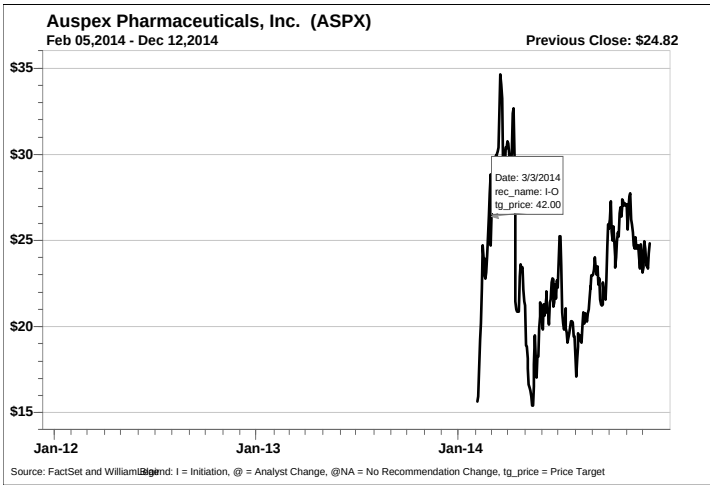
DOW JONES: 17,068.87
S&P 500: 1,972.74
NASDAQ: 4,547.84



Current Rating Distribution (as of 11/30/14)

Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	64	Outperform (Buy)	16
Market Perform (Hold)	31	Market Perform (Hold)	3
Underperform (Sell)	1	Underperform (Sell)	0

*Percentage of companies in each rating category that are investment banking clients, defined as companies for which William Blair has received compensation for investment banking services within the past 12 months.

The compensation of the research analyst is based on a variety of factors, including performance of his or her stock recommendations; contributions to all of the firm's departments, including asset management, corporate finance, institutional sales, and retail brokerage; firm profitability; and competitive factors.

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Company Profile: The William Blair research philosophy is focused on quality growth companies. Growth companies by their nature tend to be more volatile than the overall stock market. Company profile is a fundamental assessment, over a longer-term horizon, of the business risk of the company relative to the broader William Blair universe. Factors assessed include: 1) durability and strength of franchise (management strength and track record, market leadership, distinctive capabilities); 2) financial profile (earnings growth rate/consistency, cash flow generation, return on investment, balance sheet, accounting); 3) other factors such as sector or industry conditions, economic environment, confidence in long-term growth prospects, etc. Established Growth (E) – Fundamental risk is lower relative to the broader William Blair universe; Core Growth (C) – Fundamental risk is approximately in line with the broader William Blair universe; Aggressive Growth (A) – Fundamental risk is higher relative to the broader William Blair universe.

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