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Zacks Small-Cap Research

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Interleukin Genetics (ILIU-OTC)

ILIU: Q3 Results. Expect P/U in PerioPredict Activity Heading Into 2016

Current Recommendation	**Buy**
Prior Recommendation	Hold
Date of Last Change	03/28/2011
Current Price (11/20/15)	$0.10
Target Price	**$0.30**

OUTLOOK

Key UofM PST (periodontal disease) test study results were overwhelmingly positive and published in June 2013. PerioPredict launched in early 2014. Revenue has been immaterial but indications are that feedback from insurers, employer groups and patients is positive. Brought on new CEO, benefits consulting firm and revised strategy in early 2015 in order to help speed adoption of PerioPredict. Gameplan is to leverage evidence showing better dental care = lower medical costs. Company implementing 2-phased approach: target large self-insured employers for implementation into wellness programs and insurance carriers for coverage under new or modified plans. Adding personnel to facilitate strategy. New iron in the fire with collaboration with ISIS Pharma for use of Heart Health test. Other CVD relationships could follow. Another high potential pipeline test, for OA, also addresses increasing demand for personalized medicine and companion diagnostics – just signed agreement with NYU to develop and commercialize an OA test.

SUMMARY DATA

52-Week High	**$0.46**
52-Week Low	**$0.05**
One-Year Return (%)	**-40.70**
Beta	**0.58**
Average Daily Volume (sh)	**20,604**
Shares Outstanding (mil)	**173**
Market Capitalization ($mil)	**$14**
Short Interest Ratio (days)	**3.49**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**44**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-9.2**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**N/A**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in '000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	488 A	529 A	472 A	322 A	1,810 A
2015	403 A	376 A	296 A	310 E	1,385 E
2016					2,812 E
2017					5,839 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.01 A	-$0.01 A	-$0.01 A	-$0.01 A	-$0.05 A
2015	-$0.01 A	-$0.01 A	-$0.01 A	-$0.01 E	-$0.05 E
2016					-$0.03 E
2017					-$0.02 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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Q3 2015:

Interleukin reported financial results for the third quarter ending September 30th. The majority of revenue continues to come from the Weight Management test although sales of the product continue to slide, including a 23% contraction from Q2 of this year. We continue to expect little to no growth in revenue of the Weight Management test from the Amway channel, where sales began to soften shortly following Amway's decision to include the Weight Management test as a promotional bundle, which took effect in early 2013. We also do not expect any material increase in total sales until there is traction from new products, with PerioPredict being the candidate that likely holds the most promise to significantly jump-start the growth curve. And ILIU does have other pipeline candidates that could make a contribution – and potentially in the near term, including companion diagnostics for cardiovascular disease (CVD) and osteoarthritis.

While the company did not hold a Q3 call, management did provide an update on the Q2 call relative to their revamped plan to drive adoption of PerioPredict and outlined potential opportunities for other of their tests.

PerioPredict: *Linking dental care and medical savings…*

As a reminder, Mark Carbeau, who was appointed CEO in April, recently laid out a somewhat revised / enhanced strategy for the initial commercialization of PerioPredict aimed at increasing early adoption. Employee Benefit Consulting Group (EBCG), which works with employers and insurers to help align benefit packages with the needs of employer groups and their employees, was brought on to help with implementation.

A major focus of the new strategy to help drive adoption of PerioPredict is to leverage evidence that shows that proper dental care can reduce medical expenses and communicate this message to stakeholders (employers, employer groups, insurance carriers, individuals). As support for pursuing this strategy ILIU cites a major study led by Dr. Marjorie Jeffcoat, Professor of Periodontology at the University of Pennsylvania School of Dentistry which evaluated the connection between periodontal disease treatment and medical costs.

The study looked at five years' worth of medical and dental records data from almost 339k patients. It compared the medical treatment and related costs of individuals that completed treatment and maintenance of gum disease with those that did not. Subsets included a.) diagnosis of at least one specified medical condition and b.) evidence of periodontal disease. Chronic conditions included cerebral vascular disease (stroke), coronary artery disease and type-2 diabetes. Results, which were published in 2014 in the American Journal of Preventive Medicine in an article titled *Impact of Periodontal Therapy on General Health* and presented by Dr. Jeffcoat at the American Association of Dental Research meeting in Charlotte that same year, showed that for individuals that completed treatment and maintenance of gum disease as compared to those that didn't had;

- annual medical cost savings of
  - almost $5,700 for those with stroke (41% reduction)
  - almost $1,100 for those with coronary artery disease (11% reduction)
  - over $2,800 for those with diabetes (40% reduction)
  - over $2,400 for women who were pregnant (74% reduction)

- annual hospital reductions of
  - 21% for those with stroke
  - 29% for those with heart disease
  - 39% for those with diabetes

All differences were statistically significant at $p<0.05$. The study also looked at those with rheumatoid arthritis although this population did not show a statistically significant reduction in medical costs.

Table 3 Chronic medical conditions: comparison of costs and hospitalizations

	Chronic systemic disease							
	Type 2 diabetes		**Cerebral vascular disease**		**Coronary artery disease**		**Rheumatoid arthritis**	
Periodontal treatment								
Total number of qualifying subjects in Year 0 (2005)	91,242		13,007		8,458		81,439	
ICD-9 codes for inclusion in cohort	250–25099, 3572–35729, 3620–36209, 36641, 6480		433, 434		411, 413, 414, 4292		7140, 7141, 7142, 71481	
Periodontal treatment received	Untreated	Treated	Untreated	Treated	Untreated	Treated	Untreated	Treated
Number in cohort	90,329	913	12,868	139	8,368	90	80,903	536
Percentage periodontally treated	1.0%		1.1%		1.1%		0.7%	
OUTCOMES								
Total medical costs								
Total medical costs per subject per year (mean 2006–2009)	$7,056	$4,216	$13,895	$8,214	$10,222	$9,133	$9,218	$8,637
Annual reduction with treatment	$2,840 (40.2%)		$5,681 (40.9%)		$1,090 (10.7%)		$581 (6.3%)	
Significance, Wilks's lambda	***p*<0.04**		***p*<0.04**		***p*<0.04**		NS	
Hospital admission								
Inpatient admissions per 1,000 subjects per year (mean 2006–2009)	66.6	40.4	444.4	350.0	65.2	46.6	142.7	136.3
Annual reduction with treatment	26.3	(39.4%)	94.4	(21.2%)	18.7	(28.6%)	6.4	(4.5%)
Significance, Wilks's lambda	***p*<0.05**		***p*<0.002**		***p*<0.01**		NS	

SOURCE: Jeffcoat, et al. AJPM. August 2014, Vol. 47, Issue2 Pgs 166-174

So to leverage this type of evidence that proper dental care can reduce medical expenses ILIU and EBCG are targeting both large employers who self-insure and insurance carriers. The initial focus, and likely the lower hanging fruit, is to encourage PerioPredict testing of individuals with chronic conditions such as CVD and type-2 diabetes as this is where the evidence shows more informed dental care can reduce medical costs.

ILIU and EBCG are dedicating most of their initial focus on employers as they believe the sales and adoption cycle may be quicker, given that there are less structural hurdles to overcome (as compared to insurance carriers which requires a modification to plans and have more red tape in general).

On the large-employer side, the value proposition is that PerioPredict can fit into wellness programs (similar to smoking cessation) – essentially that if employers sponsor (or perhaps co-sponsor with employees bearing some of the cost) PerioPredict testing that this cost will be more than recouped in lower medical costs and less employee downtime and missed worked days. The employer then may coordinate with their dental carrier to modify coverage, if appropriate. This, as outlined on the Q1 call in May, is still expected to follow a "phased-in" approach whereby, for instance, wellness plans incorporating PerioPredict might initially target high-risk groups (such as those identified in the Jeffcoat study) and over time expand to a greater portion of the employee population.

On the insurance carrier side, ILIU and EBCG have had and continue to have discussions with various carriers in incorporating coverage of PerioPredict in their plans. As noted the insurance-carrier sales cycle is anticipated to be longer – management noted that carriers want to see data-driven pilot and demonstration programs to assess the potential benefits. This, along with various decision-making layers at these large carriers as well as requisite time for new plan design, implementation and the fact that enrollment in new plans is typically a first-of-the-year event, means the insurance carrier channel is likely to be a more drawn out process.

On the Q2 call management noted that the message of reducing health care costs through better dental care is resonating with both employers and insurance carriers. But, clearly, management expects the sales and adoption process to take time and again reiterated that they do not expect significant PerioPredict revenue in 2015. They also noted that to facilitate their PerioPredict-related strategy that they intend to bring on additional sales and payer-relations personnel as well as potential increasing their benefits consulting capabilities.

OA: Collaboration with NYU to bring OA test to market

In July ILIU announced an agreement with NYU School of Medicine to develop, and eventually commercialize, a test to identify people with increased risk for progression of osteoarthritis. The companies will continue to build on their already established clinical evidence that shows a relationship between certain interleukin markers and OA progression. They jointly own a patent titled, *Detecting Genetic Predisposition to Osteoarthritis Associated Conditions.*

ILIU, in collaboration with New York University Hospital for Joint Diseases, conducted studies which identified certain genetic markers as being highly predictive of progression of OA. Results of one of these studies, done also in collaboration with Duke University, which demonstrated an association between three interleukin genes and severe knee OA, was published in the online version of the Annals of Rheumatic Disease in late 2009.

While earlier thinking was that such a test could have appeal with drug companies for use to screen patients for inclusion in clinical trials to ensure only patients expected to suffer from severe cases of the disease were enrolled, ILIU indicated on the Q2 call that they believe the clinical channel may also hold commercial promise for the test. Clearly OA represents a significant market.

As a background; OA is a degenerative disease which involves breakdown of cartilage in the joints, causing pain, stiffness and in severe cases, loss of movement. It is the most common form of arthritis, afflicting an estimated 27 million people in the U.S. and 8 million in the U.K. OA is the leading cause of chronic disability in the United States and usually affects the hands, feet, spine, hips and knees. Similar to osteoporosis, OA is most common in the elderly and women. There is no cure for the disease and severe cases of OA can result in joint replacement surgery. Almost 800k Americans undergo hip or knee replacement surgery every year with OA cited as one of the primary reasons. But while OA is progressive, development of the disease can be highly variable from person to person and not all cases result in a severe state. As such, we think that is reasonable to think that a reliable predictor of risk of OA progression could have real appeal in the clinical community.

CVD: Looking to expand CVD companion diagnostics opportunities

Management is also looking to expand their shots on goal in the CVD companion diagnostics area. As a reminder ILIU's Heart Health Genetic Test was used in a clinical trial to assess whether interleukin-1 (IL-1) genotype status can help predict risk of coronary artery disease and cardiovascular events. A manuscript of the study, titled *Pro-Inflammatory Interleukin-1 Genotypes Potentiate the Risk of Coronary Artery Disease and Cardiovascular Events Mediated by Oxidized Phospholipids and Lipoprotein (a)*, was published in the May 2014 issue of the Journal of the American College of Cardiology.

IL-1 genotypes oxidized phospholipids (OxPLs) and lipoprotein (Lp)(a) levels were measured in 499 patients. OxPLs and Lp(a) are inflammatory mediators, higher levels of which are associated with a higher risk of cardiovascular events. Results of the study showed a link between IL-1 genotype status, as measured by Interleukin's Heart Health Genetic Test, OxPLs, LP(a) and risk of coronary artery disease (CAD).

Success of this study apparently resulted in a relationship with Isis Pharmaceuticals (ISIS) whereby ILIU will provide genetic testing using a panel of its genetic tests for two separate studies, a phase I study and a phase II study. The phase II study is for Isis' ISIS-APO(a), which is being developed for the treatment of patients with high lipoprotein ((LP)(a)).

ILIU is looking for other opportunities similar to this ISIS relationship to leverage their technology in the CVD companion diagnostics space. And while Interleukin's major focus remains with commercialization of its

PerioPredict genetic test for periodontal disease, we view any and all opportunities to leverage their technology and sales and lab infrastructure to increase the revenue shots on goal as positive developments. And it is possible that these types of companion diagnostic relationships eventually turn into significant business opportunities – particularly if their technology is used, for example, to screen for enrollment of large CVD clinical trials.

Revenue
Q3 revenue of $296k was down 21% sequentially, down 37% yoy and about 18% lower than our $361k estimate. Included in the revenue is $39k in "breakage" – related to an accounting change that ILIU began to recognize in Q4 2013 and allows for the recognition of years-earlier deferred revenue from test kits that have yet to be sent back to ILIU for processing (i.e- given that it's unlikely these test kits will ever be returned for processing which is when ILIU typically recognizes revenue - ILIU can go ahead and recognize this as revenue).

GM / Operating Expenses / EPS
Q3 gross margin was negative 9%, down from 24% in the comparable year-earlier period and 12% in Q2 of this year. GM has contracted significantly with the recent slide in revenue due to less revenue to cover fixed manufacturing costs. Based on historical numbers as well as the most recent period, it appears ~$300k in revenue is the approximate level of break-even gross profit. OpEx was $1.8M, up from $1.6M in Q3 2014 but down from $2.0M in Q2 2015 and better than our $2.0M estimate. The yoy increase is mostly related to bringing on the new CEO (and Dr. Kornman continuing to serve as Chief Scientific Officer). We expect OpEx to remain at higher levels than in the recent past with additions to the sales and support staff.

Net loss and EPS were $2.0M and ($0.01), which compares to $1.5M / ($0.01) in Q3 2014, $2.2M / ($0.01) in Q2 2015 and our estimate of $2.1M / ($0.01) – with the slight beat to our net loss number coming from lower than anticipated operating expenses.

Cash
Cash used in operating activities was $1.4M in Q3. Ex-changes in working capital cash used was $1.7M. In December ILIU raised $10M from equity and debt. $5 million of which came via the sale of 50.1 million shares of common stock (at $0.1003/share) with 100% warrant coverage and $5 million from a 45-month loan. Bay City Capital, a major life sciences investment firm with approximately $1.3 billion in committed capital, was the majority investor in the $5 million equity raise taking 53% (26.5M shares). The loan comes from Horizon Technology Finance Corporation, is payable in 45 monthly installments (interest only for first 15 months) and bears interest at 1-month LIBOR plus 8.50%. ILIU expects the current cash balance, which was $6.3M at Q3 quarter-end, to fund the company into the second half of 2016.

OUTLOOK / RECOMMENDATION

We continue to believe that the major near and mid-term growth driver of the company lies with PerioPredict. We think the Weight Management test (the prior major growth driver and current most significant revenue contributor) will experience continued contraction. We have yet to model any contribution from other pipeline products including the OA test, which could provide some upside to our longer-dated estimates.

We expect a greater rate of revenue growth to materialize in 2016 as ILIU begins to realize benefits of increased patient enrollments in insurance plans and from employer wellness programs related to PerioPredict. We also could see some incremental revenue from the ISIS relationship or other similar agreements that could happen in the future although we have yet to include these in our forecasts – this will be updated if and when we feel it is appropriate.

We have made some moderate downward adjustments to our revenue estimates as well as gross margins as a result of extension of the anticipated runway for more substantial commercialization of PerioPredict. We look for revenue and EPS of $1.4 million / ($0.05) and $2.8 million / ($0.03) in 2015 and 2016, respectively. We are maintaining our Buy recommendation. Our per-share price target has moved from $0.35 to $0.30 as a result of the aforementioned updates to our model.

FINANCIAL MODEL

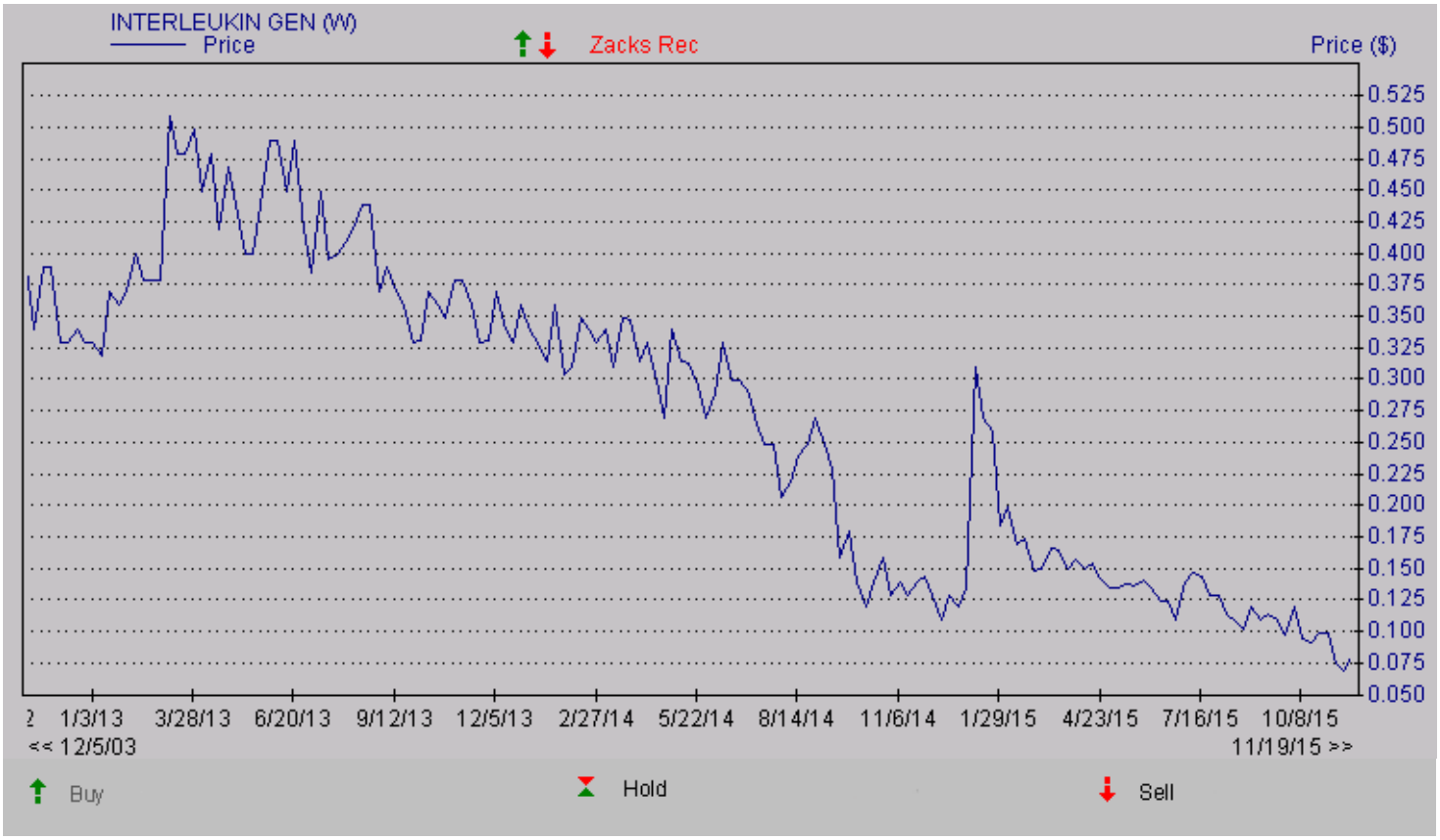
Interleukin Genetics, Inc.

	2014 A	Q1A	Q2A	Q3A	Q4E	2015 E	2016 E	2017 E	2018 E
Genetic testing	$1,641.5	$347.9	$324.8	$248.9	$287.0	$1,208.6	$2,730.0	$5,669.0	$7,207.0
YOY Growth	*-24.3%*	*-17.2%*	*-32.8%*	*-43.4%*	*-3.9%*	*-26.4%*	*125.9%*	*107.7%*	*27.1%*
Other	$168.8	$55.3	$51.2	$47.1	$23.0	$176.6	$81.9	$170.1	$216.2
Total Revenues	$1,810.3	$403.2	$376.1	$296.0	$310.0	$1,385.2	$2,811.9	$5,839.1	$7,423.2
YOY Growth	*-25.5%*	*-17.3%*	*-28.9%*	*-37.3%*	*-3.7%*	*-23.5%*	*103.0%*	*107.7%*	*27.1%*
Cost of Revenues	$1,435.4	$331.0	$331.6	$323.1	$303.8	$1,289.5	$2,148.3	$3,614.4	$4,305.5
Gross Income	$375.0	$72.2	$44.5	($27.1)	$6.2	$95.7	$663.6	$2,224.7	$3,117.7
Gross Margin	*20.7%*	*17.9%*	*11.8%*	*-9.2%*	*2.0%*	*6.9%*	*23.6%*	*38.1%*	*42.0%*
R&D	$843.1	$182.5	$384.5	$411.9	$412.0	$1,391.0	$1,404.0	$1,441.0	$1,552.0
% R&D	*46.6%*	*45.3%*	*102.3%*	*139.2%*	*132.9%*	*100.4%*	*49.9%*	*24.7%*	*20.9%*
SG&A	$5,767.2	$1,562.8	$1,655.2	$1,413.7	$1,515.0	$6,146.7	$6,218.0	$6,387.9	$6,762.5
% SG&A	*318.6%*	*387.6%*	*440.2%*	*477.6%*	*488.8%*	*443.7%*	*221.1%*	*109.4%*	*91.1%*
Amortization	$94.1	$19.4	$19.4	$19.4	$19.4	$77.7	$80.0	$80.0	$80.0
Operating Income	($6,329.4)	($1,692.6)	($2,014.7)	($1,872.2)	($1,940.2)	($7,519.6)	($7,038.4)	($5,684.3)	($5,276.8)
Operating Margin	*-349.6%*	*-419.8%*	*-535.7%*	*-632.5%*	*-626.0%*	*-542.8%*	*-250.3%*	*-97.3%*	*-71.1%*
Total Other income	($6.3)	($150.6)	($152.1)	($153.4)	($150.8)	($606.9)	($603.0)	($603.0)	($453.0)
Pre-Tax Income	($6,335.7)	($1,843.2)	($2,166.8)	($2,025.5)	($2,091.0)	($8,126.5)	($7,641.4)	($6,287.3)	($5,729.8)
Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($6,335.7)	($1,843.2)	($2,166.8)	($2,025.5)	($2,091.0)	($8,126.5)	($7,641.4)	($6,287.3)	($5,729.8)
YOY Growth	*-10.2%*	*10.7%*	*37.4%*	*39.0%*	*27.7%*	*28.3%*	*-6.0%*	*-17.7%*	*-8.9%*
Net Margin	*-350.0%*	*-457.1%*	*-576.2%*	*-684.3%*	*-674.6%*	*-586.7%*	*-271.8%*	*-107.7%*	*-77.2%*
EPS (continuing ops)	($0.05)	($0.01)	($0.01)	($0.01)	($0.01)	($0.05)	($0.03)	($0.02)	($0.02)
YOY Growth	*-34.4%*					*-8.1%*	*-30.9%*	*-25.6%*	*-13.8%*
Diluted Shares O/S	123,768	172,738	172,787	172,841	172,880	172,811	235,000	260,000	275,000

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The current distribution is as follows: Buy/Outperform- 26.0%, Hold/Neutral- 55.0%, Sell/Underperform – 15.3%. Data is as of midnight on the business day immediately prior to this publication.