

RBC Capital Markets

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Agile Therapeutics

Twirla Phase III on track - remains an attractive small cap idea

Our view: Per the 3Q update and our follow-up discussion with management, we believe progress on Twirla's Phase III study is on track. Importantly, patient recruitment efforts are expected to complete in 1Q2015 while spending came in below expectations with cash on hand expected to fund operations through Phase III data. Overall, we continue to see an attractive upside case in AGRX shares.

Key points:

Twirla Phase III study is on schedule with enrollment expected to complete in 1Q2015; the study remains on track. AGRX has activated around 50 of 70 sites with PAREXEL and continues to be diligent with recruitment. Enrollment timing of 4-6 months, which began in September, is unchanged, with the trial expected to last ~12 months. We expect data in 1Q2016 and could see a Twirla approval in 2H2016. Recall that subpar patient recruitment and loss of data were contributing factors to the prior Phase III trial that led to the CRL. The company continues to focus on patient screening and data collection methods with the deployment of E-diaries. These sites have prior experience with E-diaries, which should add to confidence regarding data collection. We continue to believe that precautions taken with the study setup and that patient screening will lead to an acceptable efficacy result in line with other approved contraceptives.

3Q spend came in lighter then expected, with AGRX ending the quarter with ~\$45.7 million in cash; we still see cash funding through data read in early 2016. We expect R&D costs to increase in 4Q sequentially over 3Q and remain elevated through the patient recruitment phase into 1Q2015, which will tail off as initial patients complete the study. Management expects cash on hand to fund operations through 1Q2016; beyond that, we could see additional capital needs should AGRX pursue commercial infrastructure build.

AGRX remains a compelling opportunity for patient investors with small cap appetite; we still think a post data read take-out is a realistic possibility. Our \$340 million peak sales estimate for lead product candidate Twirla reflects a 3% TRx penetration and a relatively modest pricing assumption; both are arguably conservative, creating what we think is a very favorable upside scenario. For each 100 basis points in TRx penetration, we see roughly \$114 million in additional peak sales and that translates into close to \$3 in NPV per share. Additionally, we still think AGRX could be a logical takeout target post positive Phase III data, possibly creating an attractive exit for investors should management choose not to commercialize it itself.

Outperform Speculative Risk

NASDAQ: AGRX; USD 6.37

Price Target USD 12.00

WHAT'S INSIDE	
☐ Rating/Risk Change	☐ Price Target Change
☐ In-Depth Report	☑ Est. Change
☐ Preview	☐ News Analysis

Scenario Analysis*

4	Downside Scenario	Current Price	Price Target	Upside Scenario	
	2.00 ↓ 69%	6.37	12.00 ↑ 88%	25.00 ↑ 292%	—

*Implied Total Returns

Key Statistics

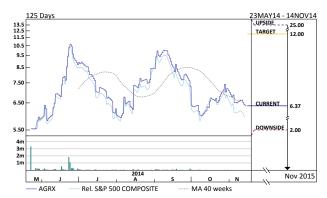
Shares O/S (MM):	20.0	Market Cap (MM):	127
Dividend:	0.00	Yield:	0.0%
		Avg. Daily Volume:	19,626

RRC Estimates

NDC Estimate	3			
FY Dec	2013A	2014E	2015E	2016E
EBITDA, Adj		(22.1)	(23.4)	(27.0)
Prev.		(26.8)	(18.4)	(25.0)
EPS, Adj Diluted		(1.11)	(1.23)	(1.39)
Prev.		(1.32)	(0.87)	(1.14)
Revenue	0.0	0.0	0.0	14.8
P/AEPS	NM	NM	NM	NM
EBITDA, Adj	Q1	Q2	Q3	Q4
2014	(2.4)A	(3.5)A	(6.0)A	(10.2)E
Prev.			(10.8)E	(10.0)E
2015	(10.3)E	(5.0)E	(4.0)E	(4.1)E
Prev.	(6.3)E	(4.3)E	(4.3)E	(3.3)E
EPS, Adj Diluted				
2014	0.01A	(0.28)A	(0.32)A	(0.52)E
Prev.			(0.55)E	(0.50)E
2015	(0.53)E	(0.27)E	(0.22)E	(0.22)E
Prev.	(0.32)E	(0.22)E		(0.13)E
All values in USD unless of	therwise noted	f.		

Target/Upside/Downside Scenarios

Exhibit 1: Agile Therapeutics



Source: Bloomberg and RBC Capital Markets estimates for Upside/Downside/Target

Target price/base case

Our base case scenario sees a \$12 share price on the following assumptions:

- Progress toward successful Phase III results and expected commercial launch by Agile in US H2/16.
- Peak US sales potential of \$340 million for Twirla reflecting 3% share of the CHC market on 4% annual pricing increases.
- Risk adjustment of 70% in our DCF while our Twirla NPV assumes a 23% discount rate on un-risk adjusted sales.
- No revenue contribution from the remainder of the pipeline and only modest benefit from existing NOLs.

Upside scenario

Our upside case scenario sees a \$25 share price on the following assumptions:

- Progress toward successful Phase III results and expected commercial launch by Agile in US H2/16.
- Peak US sales of \$617 million for Twirla reflecting 5% share of the CHC market and 5% annual pricing increases.
- Risk adjustment of 70% in our DCF while our Twirla NPV assumes a 23% discount rate on un-risk adjusted sales as the Phase III data read is expected in late 2015 (> 12 months).
- No revenue contribution from the remainder of the pipeline and only modest benefit from existing NOLs.

Downside scenario

Our downside case scenario sees a \$2 share price on an early unexpected halt to the Phase III study. In this scenario we assume modest value for platform technology, cash on hand, and existing NOLs.

Investment summary

Agile's lead product Twirla is a low-dose once-weekly contraceptive patch that we believe fills an established unmet need in the market. Twirla offers both convenience and compliance benefits that we think would appeal to a core patient base once approved. Our thesis rests on four main points:

- 1) We believe Twirla can capture 3% TRx share in the sizable \$4.2 billion CHC market that is growing annually in the midsingle digits given the unique benefits that a CHC patch product without a black box safety warning could bring.
- 2) We see a clear path to market for Twirla and expect positive Phase III data in 1Q2016, followed by approval in H2/16.
- 3) There could be additional value from the existing pipeline and platform technology that we have not ascribed value to.
- 4) We see Agile as a logical takeout candidate by an established player in contraceptives with significant marketing resources and an established specialty sales force.

Potential catalysts to focus on: 1) Phase III data readout in 1Q2016; 2) NDA approval in 2H2016; and 3) potential acquisition that could be possible post positive Phase III data.

Risks to our thesis: 1) new phase III data for Twirla is insufficient for an NDA filing; 2) additional regulatory or execution delays to launch; 3) potential for greater than expected financing needs; and 4) lack of commercial uptake or adoption below expectations.



Exhibit 2: AGRX P&L 2012 to 2017E

Agile - Income Statement	FY2012	FY2013					FY2014					FY2015	FY2016	FY2017	
(\$ in millions)	Actual	Actual	Mar-14	Jun-14	Sep-14	Dec-14E	Est.	Mar-15E	Jun-15E	Sep-15E	Dec-15E	Est.	Est.	Est.	Comments
Revenue	<u> </u>														
Twirla	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	14.8	68.0	Assume a 2H2016 launch - no generics through '22E
Other	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	Pipeline potential for lifecycle and upside
Total revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	14.8	68.0	Each 100 bps Twirla share ~\$100M in revenue
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	1.1	5.6	
Total gross profit	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	13.6	62.4	GM 90-92% - no royalty commitments
Research and development (R&D)	17.4	9.2	1.4	2.4	4.6	8.7	17.1	8.8	3.5	2.5	2.5	17.3	8.0	3.9	
General and administrative (G&A)	5.9	3.6	1.1	1.1	1.4	1.5	5.1	1.5	1.5	1.5	1.5	6.0	6.1	6.3	Should be relatively stable
Sales and marketing (S&M)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	26.5	37.8	Based on 90 reps, promo, social media, ad spend
Operating income (adjusted)	(23.3)	(12.7)	(2.4)	(3.5)	(6.0)	,	(22.2)	(10.3)	(5.0)	(4.0)	(4.1)	(23.4)	(27.1)	14.4	
Interest expense & other	(0.7)	(1.5)	(0.4)	(0.4)	(0.4)	(0.4)	(1.6)	(0.4)	(0.4)	(0.4)	(0.4)	(1.6)	(1.6)	0.0	
Interest income and other income (expense)	0.2	(0.1)	0.0	0.2	0.1	0.1	0.4	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Total interest & other	(0.5)	(1.6)	(0.4)	(0.2)	(0.3)		(1.2)	(0.3)	(0.4)	(0.4)	(0.4)	(1.5)	(1.6)	0.0	
Earnings before income taxes (adj)	(23.9)	(14.3)	(2.8)	(3.7)	(6.4)	(10.5)	(23.4)	(10.6)	(5.4)	(4.4)	(4.5)	(24.9)	(28.6)	14.4	
Income tax (adjusted)	0.0	0.0	(3.7)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Net earnings to Agile	(23.9)	(14.3)	0.8	(3.7)	(6.4)	(10.5)	(23.4)	(10.6)	(5.4)	(4.4)	(4.5)	(24.9)	(28.6)	14.4	
EPS (pro-forma), diluted	(\$603.8)	(\$289.4)	\$0.01	(\$0.28)	(\$0.32)	(\$0.52)	(\$1.11)	(\$0.53)	(\$0.27)	(\$0.22)	(\$0.22)	(\$1.23)	(\$1.39)	\$0.69	
Diluted shares outstanding	0.0	0.0	9.7	13.2	20.1	20.1	15.8	20.2	20.3	20.4	20.5	20.3	20.6	20.9	
EBITDA	(23.3)	(12.7)	(2.4)	(3.5)	(6.0)	(10.2)	(22.1)	(10.3)	(5.0)	(4.0)	(4.1)	(23.4)	(27.0)	14.4	
EBITDA margin	NM	NM	NM	NM	NM	NM NM	NM	NM	NM	NM	NM	NM	NM	21.2%	
Growth analysis Y-O-Y	FY2012	FY2013	Mar-14	Jun-14	C 44	Dec-14E	FY2014								
Revenue					Sep-14	Dec-14E	FY2014	Mar-15E	Jun-15E	Sep-15E	Dec-15E	FY2015	FY2016	FY2017	
	NM	NM	NM	NM	NM	NM	NM	NM	NM	Sep-15E NM	NM	FY2015 NM	NM	FY2017 361%	We assume 2H16 launch with peak year 2021
COGS	NM	NM	NM NM	NM NM	NM NM	NM NM	NM NM	NM NM	NM NM	NM NM	NM NM	NM NM	NM NM	361% 400%	We assume 2H16 launch with peak year 2021
COGS Gross profit	NM NM	NM NM	NM NM NM	NM NM NM	NM NM NM	NM NM NM	NM NM NM	NM NM NM	NM NM NM	NM NM NM	NM NM NM	NM NM NM	NM NM NM	361% 400% 358%	We assume 2H16 launch with peak year 2021
COGS Gross profit Research and development (R&D)	NM NM NM	NM NM NM	NM NM NM	NM NM NM	NM NM NM	NM NM NM	NM NM NM 87%	NM NM NM 531%	NM NM NM 46%	NM NM NM -46%	NM NM NM -71%	NM NM NM 1%	NM NM NM -54%	361% 400% 358% -51%	We assume 2H16 launch with peak year 2021
COGS Gross profit Research and development (R&D) General and administrative (G&A)	NM NM NM	NM NM NM	NM NM NM NM	NM NM NM NM	NM NM NM NM	NM NM NM NM	NM NM NM 87% 42%	NM NM NM 531% 40%	NM NM NM 46% 35%	NM NM NM -46% 3%	NM NM NM -71% 3%	NM NM NM 1% 18%	NM NM NM -54% 3%	361% 400% 358% -51% 2%	We assume 2H16 launch with peak year 2021
COGS Gross profit Research and development (R&D) General and administrative (G&A) Sales and marketing (S&M)	NM NM NM NM	NM NM NM NM	NM NM NM NM NM	NM NM NM NM NM	NM NM NM NM NM	NM NM NM NM NM	NM NM NM 87% 42% NM	NM NM NM 531% 40% NM	NM NM NM 46% 35% NM	NM NM NM -46% 3% NM	NM NM NM -71% 3% NM	NM NM NM 1% 18% NM	NM NM NM -54% 3% 26430%	361% 400% 358% -51% 2% 43%	We assume 2H16 launch with peak year 2021
COGS Gross profit Research and development (R&D) General and administrative (G&A) Sales and marketing (S&M) Operating income (adjusted)	NM NM NM NM NM	NM NM NM NM NM	NM NM NM NM NM NM	NM NM NM NM NM NM	NM NM NM NM NM NM	NM NM NM NM NM NM	NM NM NM 87% 42% NM	NM NM NM 531% 40% NM	NM NM NM 46% 35% NM	NM NM NM -46% 3% NM	NM NM NM -71% 3% NM	NM NM NM 1% 18% NM	NM NM NM -54% 3% 26430% NM	361% 400% 358% -51% 2% 43% -153%	We assume 2H16 launch with peak year 2021
COGS Gross profit Research and development (R&D) General and administrative (G&A) Sales and marketing (S&M) Operating income (adjusted) Net earning (adjusted)	NM NM NM NM NM NM	NM NM NM NM NM NM	NM NM NM NM NM NM NM	NM NM NM NM NM NM NM	NM NM NM NM NM NM NM	NM NM NM NM NM NM	NM NM 87% 42% NM NM	NM NM NM 531% 40% NM NM	NM NM NM 46% 35% NM NM	NM NM NM -46% 3% NM NM	NM NM NM -71% 3% NM NM	NM NM NM 1% 18% NM NM	NM NM -54% 3% 26430% NM NM	361% 400% 358% -51% 2% 43% -153% -150%	We assume 2H16 launch with peak year 2021
COGS Gross profit Research and development (R&D) General and administrative (G&A) Sales and marketing (S&M) Operating income (adjusted) Net earning (adjusted) EPS (adjusted)	NM NM NM NM NM NM NM	NM NM NM NM NM NM NM	NM NM NM NM NM NM NM NM	NM NM NM NM NM NM NM NM	NM NM NM NM NM NM NM NM	NM NM NM NM NM NM NM	NM NM NM 87% 42% NM NM NM	NM NM NM 531% 40% NM NM NM	NM NM NM 46% 35% NM NM	NM NM NM -46% 3% NM NM NM	NM NM NM -71% 3% NM NM NM	NM NM NM 1% 18% NM NM NM	NM NM NM -54% 3% 26430% NM NM	361% 400% 358% -51% 2% 43% -153% -150% NM	We assume 2H16 launch with peak year 2021
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COGS Gross profit Research and development (R&D) General and administrative (G&A) Sales and marketing (S&M) Operating income (adjusted) Net earning (adjusted) EPS (adjusted) Margin analysis Gross margin	NM NM NM NM NM NM NM NM NM	NM NM NM NM NM NM NM NM NM	NM NM NM NM NM NM NM NM NM NM	NM NM NM NM NM NM NM NM NM NM	NM NM NM NM NM NM NM NM NM NM	NM NM NM NM NM NM NM NM NM NM	NM NM NM 87% 42% NM NM NM NM	NM NM NM 531% 40% NM NM NM NM NM	NM NM NM 46% 35% NM NM NM NM	NM NM NM -46% 3% NM NM NM NM NM	NM NM NM -71% 3% NM NM NM NM	NM NM 1% 18% NM NM NM NM NM NM	NM NM NM -54% 3% 26430% NM NM NM FY2016 92%	361% 400% 358% -51% 2% 43% -153% -150% NM FY2017 92%	
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COGS Gross profit Research and development (R&D) General and administrative (G&A) Sales and marketing (S&M) Operating income (adjusted) Net earning (adjusted) EPS (adjusted) Margin analysis Gross margin R&D SG&A Sales and marketing (S&M) Operating income (adjusted) Interest expense	NM N	NM N	NM N	NM N	NM N	NM N	NM NM NM 87% 42% NM NM NM NM NM NM NM NM	NM NM NM 531% 40% NM NM NM NM NM NM NM NM NM NM NM NM	NM NM NM 46% 35% NM NM NM NM NM NM	NM NM NM -46% 3% NM NM NM NM NM Sep-15E NM NM NM	NM NM NM -71% 3% NM Dec-15E NM NM NM NM	NM NM NM 1% 18% NM NM NM NM NM FY2015 NM NM NM	NM NM NM -54% 3% 26430% NM NM NM FY2016 92% 54% 42%	361% 400% 358% -51% 2% 43% -153% -150% NM FY2017 92% 6% 9% 56% 21%	
COGS Gross profit Research and development (R&D) General and administrative (G&A) Sales and marketing (S&M) Operating income (adjusted) Net earning (adjusted) EPS (adjusted) Margin analysis Gross margin R&D SG&A Sales and marketing (S&M) Operating income (adjusted)	NM N	NM N	NM N	NM N	NM N	NM N	NM NM NM 87% 42% NM	NM NM NM 531% 40% NM NM NM NM NM NM NM NM NM NM NM NM NM	NM NM NM 46% 35% NM NM NM NM NM NM NM NM NM	NM NM NM -46% 3% NM NM NM NM NM NM NM NM NM NM	NM NM NM -71% 3% NM NM NM NM NM NM NM NM NM NM NM NM	NM NM 1% 18% NM NM NM NM NM NM NM NM NM NM NM	NM NM -54% 3% 26430% NM NM NM S2% 54% 42% 180% -183% -11%	361% 400% 358% -51% 2% 43% -153% -150% NM FY2017 92% 6% 9% 956% 21%	

Source: Company data, RBC Capital Markets Research

Valuation

Our \$12 price target is based equally on our DCF and NPV valuation. Given that the primary value of Agile comes from its lead product candidate Twirla, we think that taking a blended approach is warranted.

Our DCF valuation of \$12 per share reflects our risk adjusted forecasts in the US for Twirla. Our Twirla NPV has expected sales and marketing expenses for commercialization, R&D spending to support expected pipeline studies, and the full organizational cost structure applied against

Our NPV reflects full US sales for Twirla in the US. Our \$12 value is based on a 14% WACC and an explicit forecast through 2022 beyond which we assume a terminal growth rate of -30% assuming generic threats in that time period.

Price target impediments

Price target impediments include but are not limited to: 1) new Phase III study results may still show unacceptable efficacy with high Pearl Index levels; 2) other potential deficiencies that may block an NDA submission; 3) low market acceptance and product uptake at commercialization; 4) potential need for additional financing; and 5) competitive risks from other branded or generic contraceptives.

Company description

Agile Therapeutics (AGRX) is development-stage women's health specialty pharmaceutical company focused on branded contraceptive patches. The company is based in Princeton, New Jersey, and, as of May 20, 2014, employed 11 full-time employees. Agile's lead product candidate, Twirla™ (AG200-15), is a once-weekly prescription contraceptive patch currently in Phase 3 clinical development. Twirla is a combination hormonal contraceptive patch that contains ethinyl estradiol (EE), a synthetic estrogen, and levonorgestrel (LNG), a progestin, which have established records of efficacy and safety in existing contraceptives. Twirla is designed to consistently deliver the hormones over a seven-day period at levels comparable to currently available oral contraceptives. Agile expects Phase III data by 1Q 2016, and approval in H2/16. Additional pipeline products include: 1) AG200-ER, an extended cycle regimen patch; 2) AG200-SP, a 28-day regimen that includes a shortened hormone-free interval; and 3) a progestin-only candidate, AG890, for women unable or unwilling to take estrogen.



Required disclosures

Conflicts disclosures

The analyst(s) responsible for preparing this research report received compensation that is based upon various factors, including total revenues of the member companies of RBC Capital Markets and its affiliates, a portion of which are or have been generated by investment banking activities of the member companies of RBC Capital Markets and its affiliates.

Please note that current conflicts disclosures may differ from those as of the publication date on, and as set forth in, this report. To access current conflicts disclosures, clients should refer to https://www.rbccm.com/GLDisclosure/PublicWeb/Disclosure/PublicWeb/DisclosureLookup.aspx?entityId=1 or send a request to RBC CM Research Publishing, P.O. Box 50, 200 Bay Street, Royal Bank Plaza, 29th Floor, South Tower, Toronto, Ontario M5J 2W7.

A member company of RBC Capital Markets or one of its affiliates managed or co-managed a public offering of securities for Agile Therapeutics in the past 12 months.

A member company of RBC Capital Markets or one of its affiliates received compensation for investment banking services from Agile Therapeutics in the past 12 months.

RBC Capital Markets, LLC makes a market in the securities of Agile Therapeutics.

Royal Bank of Canada, together with its affiliates, beneficially owns 1 percent or more of a class of common equity securities of Agile Therapeutics.

RBC Capital Markets has provided Agile Therapeutics with investment banking services in the past 12 months.

Explanation of RBC Capital Markets Equity rating system

An analyst's 'sector' is the universe of companies for which the analyst provides research coverage. Accordingly, the rating assigned to a particular stock represents solely the analyst's view of how that stock will perform over the next 12 months relative to the analyst's sector average. Although RBC Capital Markets' ratings of Top Pick (TP)/Outperform (O), Sector Perform (SP), and Underperform (U) most closely correspond to Buy, Hold/Neutral and Sell, respectively, the meanings are not the same because our ratings are determined on a relative basis.

Ratings

Top Pick (TP): Represents analyst's best idea in the sector; expected to provide significant absolute total return over 12 months with a favorable risk-reward ratio.

Outperform (O): Expected to materially outperform sector average over 12 months.

Sector Perform (SP): Returns expected to be in line with sector average over 12 months.

Underperform (U): Returns expected to be materially below sector average over 12 months.

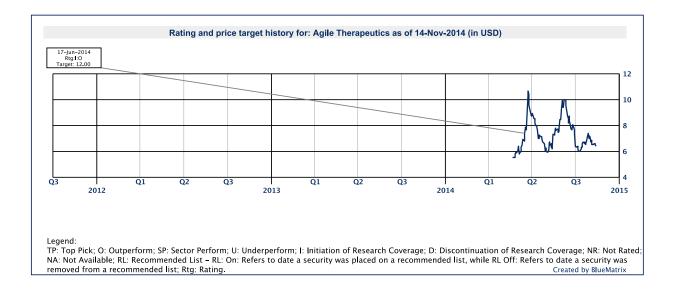
Risk Rating

As of March 31, 2013, RBC Capital Markets suspends its Average and Above Average risk ratings. The **Speculative** risk rating reflects a security's lower level of financial or operating predictability, illiquid share trading volumes, high balance sheet leverage, or limited operating history that result in a higher expectation of financial and/or stock price volatility.

Distribution of ratings

For the purpose of ratings distributions, regulatory rules require member firms to assign ratings to one of three rating categories - Buy, Hold/Neutral, or Sell - regardless of a firm's own rating categories. Although RBC Capital Markets' ratings of Top Pick(TP)/ Outperform (O), Sector Perform (SP), and Underperform (U) most closely correspond to Buy, Hold/Neutral and Sell, respectively, the meanings are not the same because our ratings are determined on a relative basis (as described below).

	Distribution	n of ratings		
	RBC Capital Market	s, Equity Research		
	As of 30-5	Sep-2014		
			Investment Bank	ing
			Serv./Past 12 Mo	os.
Rating	Count	Percent	Count	Percent
BUY [Top Pick & Outperform]	858	52.35	308	35.90
HOLD [Sector Perform]	683	41.67	151	22.11
SELL [Underperform]	98	5.98	8	8.16



References to a Recommended List in the recommendation history chart may include one or more recommended lists or model portfolios maintained by RBC Wealth Management or one of its affiliates. RBC Wealth Management recommended lists include a former list called the Prime Opportunity List (RL 3), the Guided Portfolio: Prime Income (RL 6), the Guided Portfolio: Large Cap (RL 7), the Guided Portfolio: Dividend Growth (RL 8), the Guided Portfolio: Midcap 111 (RL 9), the Guided Portfolio: ADR (RL 10), and the Guided Portfolio: Global Equity (U.S.) (RL 11). RBC Capital Markets recommended lists include the Strategy Focus List and the Fundamental Equity Weightings (FEW) portfolios. The abbreviation 'RL On' means the date a security was placed on a Recommended List. The abbreviation 'RL Off' means the date a security was removed from a Recommended List.

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