COWEN
AND COMPANY

Biotechnology

Relypsa

Equity Research

Company Update

June 9, 2014

Price: $24.65 (06/5/2014)

Price Target: NA

OUTPERFORM (1)

Eric Schmidt, Ph.D.
646.562.1345
eric.schmidt@cowen.com

Cristina Ghenoiu, Ph.D.
646.562.1401
cristina.ghenoiu@cowen.com

Key Data

Symbol	NASDAQ: RLYP
52-Week Range:	$52.74 - 11.00
Market Cap (MM):	$834.3
Net Debt (MM):	$(78.8)
Cash/Share:	$3.19
Dil. Shares Out (MM):	29.7
Enterprise Value (MM):	$768.3
ROIC:	NA
ROE (LTM):	NA
BV/Share:	$2.05
Dividend:	NA

FY (Dec)	2013A	2014E	2015E
Earnings Per Share			
Q1	$(3.90)	$(0.54)A	-
Prior Q1	-	*$(0.52)*	-
Q2	$(4.79)	$(0.57)	-
Prior Q2	-	*$(0.61)*	-
Q3	$(4.84)	$(0.67)	-
Prior Q3	-	*$(0.72)*	-
Q4	$(0.68)	$(0.73)	-
Prior Q4	-	*$(0.79)*	-
Year	$(22.42)	$(2.52)	$(2.85)
Prior Year	-	*$(2.64)*	-
P/E	NM	NM	NM
Consensus EPS	$(22.42)	$(2.54)	$(3.02)

Consensus source: Thomson Reuters

Patiromer NDA On Track, Commercial Prep Underway

The Cowen Insight

Last week, we hosted senior management for a series of meetings with investors. Relypsa will submit an NDA for patiromer for the treatment of hyperkalemia in Q3, and is beginning to focus on commercial readiness. We believe patiromer has near $1B potential in an untapped U.S. market, and expect RLYP shares to outperform as the launch nears.

NDA Filing On Track, Approval Appears Low Risk

With last month's completion of a Phase I onset of action study, Relypsa has all the information needed to file patiromer's NDA. The company is pleased with patiromer's speed of onset (<24 hours), and believes the drug's potency and predictable potassium-lowering properties will allow it to compete well versus other binders in the acute setting, though we continue to expect patiromer will have a far bigger role in the management of chronic hyperkalemia. Approval of patiromer's NDA appears low risk given (1) development was successfully completed under an SPA, (2) the drug's safety profile was clean with low rates of GI and other adverse events, and (3) patiromer is non-absorbed with a low propensity for drug-drug interactions. Management is planning for an AdCom meeting, but is not sure whether one will be required. We note that Renagel and Sensipar, patiromer's closest therapeutic analogs, were approved without a panel.

Manufacturing In Place, Commercial Planning Underway

Last month, Relypsa signed a commercial API supply agreement with DSM. With two suppliers in the fold (Lanxess is the other), each of which has produced material for patiromer's clinical trials and each of which has operated at commercial scale, management is feeling good about its ability to deliver gross margins into the low 80%'s over time. Relypsa is also ramping up efforts to build awareness of patiromer via publications and presentations at medical meetings. The company is hiring a Chief Commercial Officer, to be followed by a medical affairs team, and will eventually make contingent offers to a sales team. Meanwhile, management is exploring EMA approval requirements (additional studies may or may not be needed), as well as partnership opportunities in Japan and possibly Europe.

Thoughts On A Potential Competitor

The over >2MM U.S. patients with no good options for managing their hyperkalemia may soon have the benefit of two novel therapies. ZS Pharma intends to file an NDA on ZS-9 (zirconium silicate) in H1:15. While we know less about ZS-9's long-term safety profile, we assume that ZS-9 will eventually be approved, and that a second player won't negatively impact (and might even facilitate) patiromer's ability to capture the 5-10% market share we model. Relative to patiromer, ZS Pharma's lone advantage may be its greater convenience (once daily following an initial 3x/day loading period). However, Relypsa has already accumulated data that indicate patiromer is as effective QD as BID, and plans to initiate a study to support once daily approval around YE.

At A Glance

Our Investment Thesis

Relypsa plans to file an NDA on patiromer for the treatment of hyperkalemia in Q3:14. The addressable U.S. market opportunity is large, with over 2M moderate to severe hyperkalemia patients presenting to specialist physicians. We model sales ramping to nearly $1B over time assuming fairly modest market penetration estimates (~10% market share). We expect shares to outperform as patiromer advances toward potential FDA approval in 2015.

Forthcoming Catalysts

- File patiromer NDA
- Possible FDA AdCom meeting on patiromer

Base Case Assumptions

- Patiromer is approved for treating hyperkalemia
- Patiromer achieves 2018 U.S. sales of $200MM

Upside Scenario

- Patiromer's launch proceeds better than expected
- Relypsa is able to monetize patiromer's value outside the U.S.
- Relypsa is able to generate other interesting drug candidates

Downside Scenario

- Patiromer encounters regulatory delays or setbacks
- Patiromer's side effect profile worsens
- Patiromer's launch falls short of expectations

Price Performance

Source: Bloomberg

Company Description

Relypsa is developing patiromer for the treatment of hyperkalemia (high levels of potassium in the blood). Patients with chronic kidney disease and heart failure are known to have elevated levels of potassium, which carry risk of cardiac arrhythmia and sudden death. Unfortunately, RAASi therapies (ARBs, ACE inhibitors, AAs) that are the standard of care for treating these diseases further exacerbate the situation by increasing blood levels of potassium. As a result, RAASi therapies are often under-dosed, providing for sub optimal control of the underlying disease. Patiromer is a non-absorbed polymer that binds potassium in the gut and excretes it from the body. In an SPA-sponsored Phase III trial, patiromer reduced serum potassium to normal ranges in 76% of patients. Unlike other potassium lowering therapeutics, the drug appears well tolerated and safe for chronic use. Therefore, we believe patiromer represents an approvable therapy for an unmet need.

Analyst Top Picks

	Ticker	Price (06/5/2014)	Price Target	Rating
Sunesis Pharmaceuticals	SNSS	$5.17	$NA	Outperform
Relypsa	RLYP	$24.65	$NA	Outperform
Ultragenyx	RARE	$34.28	$NA	Outperform

Investment Thesis

Relypsa is developing patiromer for the treatment of hyperkalemia (high levels of potassium in the blood). Patients with chronic kidney disease and heart failure are known to have elevated levels of potassium, which carry risk of cardiac arrhythmia and sudden death. Unfortunately, RAASi therapies (ARBs, ACE inhibitors, AAs) that are the standard of care for treating these diseases further exacerbate the situation by increasing blood levels of potassium. As a result, RAASi therapies are often under dosed, providing for sub optimal control of the underlying disease. Patiromer is a nonabsorbed polymer that binds potassium in the gut and excretes it from the body. In an SPA-sponsored Phase III trial, patiromer reduced serum potassium to normal ranges in 76% of patients. Unlike other potassium lowering therapeutics, the drug appears well tolerated and safe for chronic use. Therefore, we believe patiromer represents an approvable therapy for an unmet need. Relypsa plans to file an NDA on patiromer for the treatment of hyperkalemia in Q3:14. The addressable U.S. market opportunity is large, with over 2M moderate to severe hyperkalemia patients presenting to specialist physicians. We model sales ramping to nearly $1B over time assuming fairly modest market penetration estimates (~10% market share). We expect RLYP shares to outperform patiromer advances toward potential FDA approval in 2015.

Upcoming Relypsa Milestones

Event	Timing
Submit patiromer NDA to the FDA	Q3:14
Additional publications and medical meeting presentations on patiromer	2014-2015
Potential selection of additional polymer-based development candidates	2015
Identify potential ex-U.S. development strategy for patiromer	2015
Begin trials on once daily formulation of patiromer	2015
Possible FDA advisory panel for patiromer	Mid:15
U.S. approval and launch of patiromer	Q4:15

Source: Cowen and Company

Relypsa Quarterly P&L ($MM)

	Q1:13A	Q2:13A	Q3:13A	Q4:13A	2013A	Q1:14A	Q2:14E	Q3:14E	Q4:14E	2014E	2015E
Patiromer Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	5.0
Total Revenue	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**5.0**
Y/Y growth											
COGS	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0
GMs											*60%*
R&D	16.3	19.6	12.2	10.9	59.0	10.9	14.2	16.0	17.0	58.1	56.0
SG&A	2.0	3.5	2.7	3.7	11.9	4.8	4.7	6.5	8.0	24.0	51.0
Total Expenses	**18.3**	**23.1**	**14.8**	**14.6**	**70.9**	**15.7**	**18.9**	**22.5**	**25.000**	**82.1**	**109.0**
Operating Income/Loss	**(18.3)**	**(23.1)**	**(14.8)**	**(14.6)**	**(70.9)**	**(15.7)**	**(18.9)**	**(22.5)**	**(25.0)**	**(82.1)**	**(104.0)**
Non-Operating Income	(2.5)	(2.5)	(10.8)	5.6	(10.3)	(0.4)	(0.4)	(0.4)	(0.4)	(1.6)	(1.6)
Pre-tax Income/Loss	**(20.8)**	**(25.6)**	**(25.6)**	**(9.1)**	**(81.2)**	**(16.1)**	**(19.3)**	**(22.9)**	**(25.4)**	**(83.7)**	**(105.6)**
Tax rate (%)	0%	0%	0%	0%	0%	0%	0%	8%	0%	0%	0%
Provision for income taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income (Loss)	**(20.8)**	**(25.6)**	**(25.6)**	**(9.1)**	**(81.2)**	**(16.1)**	**(19.3)**	**(22.9)**	**(25.4)**	**(83.7)**	**(105.6)**
GAAP EPS	**($3.90)**	**($4.79)**	**($4.84)**	**$ (0.68)**	**$ (22.42)**	**($0.54)**	**($0.57)**	**($0.67)**	**($0.73)**	**($2.52)**	**($2.85)**
Diluted Shares	5.3	5.3	5.3	13.4	3.6	29.7	33.9	34.3	35.0	33.2	37.0

Source: Cowen and Company

Relypsa Annual P&L Model ($MM)

	2013A	2014E	2015E	2016E	2017E	2018E
Patiromer Revenue	0.0	0.0	5.0	50.0	125.0	200.0
Total Revenue	**0.0**	**0.0**	**5.0**	**50.0**	**125.0**	**200.0**
Y/Y growth	0%	0%	0%	900%	150%	60%
COGS	0.0	0.0	2.0	17.5	37.9	46.2
R&D	59.0	58.1	56.0	60.0	62.0	64.0
SG&A	11.9	24.0	51.0	88.0	95.0	100.0
Total Expenses	**70.9**	**82.1**	**109.0**	**165.5**	**194.9**	**210.2**
Operating Income/Loss	(70.9)	(82.1)	(104.0)	(115.5)	(69.9)	(10.2)
Non-Operating Income	(10.3)	(1.6)	(1.6)	(1.6)	(2.0)	(2.0)
Pre-tax Income/Loss	(81.2)	(83.7)	(105.6)	(117.1)	(71.9)	(12.2)
Tax rate (%)	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Provision for income taxes	0.0	0.0	0.0	0.0	0.0	0.0
Net Income (Loss)	(81.2)	(83.7)	(105.6)	(117.1)	(71.9)	(12.2)
GAAP EPS	**($22.42)**	**($2.52)**	**($2.85)**	**($3.00)**	**($1.80)**	**($0.30)**
Diluted Shares	3.6	33.2	37.0	39.0	40.0	41.0

Source: Cowen and Company

Valuation Methodology And Risks

Valuation Methodology

Biotechnology:

In calculating our 12-month target price, we employ one or more valuation methodologies, which include a discounted earnings analysis, discounted cash flow analysis, net present value analysis and/or a comparable company analysis. These analyses may or may not require the use of objective measures such as price-to-earnings or price-to-sales multiples as well as subjective measures such as discount rates.

We make investment recommendations on early stage (pre-commercial) biotechnology companies based upon an assessment of their technology, the probability of pipeline success, and the potential market opportunity in the event of success. However, because these companies lack traditional financial metrics, we do not believe there are any good methodologies for assigning a specific target price to such stocks.

Investment Risks

Biotechnology:

There are multiple risks that are inherent with an investment in the biotechnology sector. Beyond systemic risk, there is also clinical, regulatory, and commercial risk. Additionally, biotechnology companies require significant amounts of capital in order to develop their clinical programs. The capital-raising environment is always changing and there is risk that necessary capital to complete development may not be readily available.

Risks To The Price Target

Relypsa has no approved products and its entire future revenue stream depends on the commercial success of patiromer, the company's only product. Patiromer is still in clinical development. Even though it has successfully completed Phase III clinical trials, unexpected safety issues could emerge, thus jeoperdizing the FDA approval process. To produce patiromer, Relypsa relies on a series of third-party manufacturers and depends on these entities to fulfill orders. In addition, patiromer sales may fall short of expectations. The drug treats hyperkalemia, a symptom that is often times induced by the administration of other drugs. The number of patients suffering from this complication may be smaller than expected.

We make investment recommendations on early stage (pre-commercial) biotechnology companies based upon a an assessment of their technology, the probability of pipeline success, and the potential market opportunity in the event of success. However, because these companies lack traditional financial metrics, we do not believe it there are any good methodologies for assigning a specific target price to such stocks.

Addendum

Stocks Mentioned In Important Disclosures

Ticker	Company Name
RLYP	Relypsa
SNSS	Sunesis Pharmaceuticals
RARE	Ultragenyx

Analyst Certification

Each author of this research report hereby certifies that (i) the views expressed in the research report accurately reflect his or her personal views about any and all of the subject securities or issuers, and (ii) no part of his or her compensation was, is, or will be related, directly or indirectly, to the specific recommendations or views expressed in this report.

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Sunesis Pharmaceuticals is or was in the past 12 months a client of Cowen and Company, LLC; during the past 12 months, Cowen and Company, LLC provided Non-Security services.

Relypsa, Ultragenyx and Sunesis Pharmaceuticals have been client(s) of Cowen and Company, LLC in the past 12 months.

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Cowen and Company, LLC. New York (646) 562-1000 **Boston** (617) 946-3700 **San Francisco** (415) 646-7200 **Chicago** (312) 577-2240 **Cleveland** (440) 331-3531 **Atlanta** (866) 544-7009 **London** (affiliate) 44-207-071-7500

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Cowen and Company Rating System effective May 25, 2013

Outperform (1): The stock is expected to achieve a total positive return of at least 15% over the next 12 months

Market Perform (2): The stock is expected to have a total return that falls between the parameters of an Outperform and Underperform over the next 12 months

Underperform (3): Stock is expected to achieve a total negative return of at least 10% over the next 12 months

Assumption: The expected total return calculation includes anticipated dividend yield

Cowen and Company Rating System until May 25, 2013

Outperform (1): Stock expected to outperform the S&P 500

Neutral (2): Stock expected to perform in line with the S&P 500

Underperform (3): Stock expected to underperform the S&P 500

Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period

Cowen Securities, formerly known as Dahlman Rose & Company, Rating System until May 25, 2013

Buy – The fundamentals/valuations of the subject company are improving and the investment return is expected to be 5 to 15 percentage points higher than the general market return

Sell – The fundamentals/valuations of the subject company are deteriorating and the investment return is expected to be 5 to 15 percentage points lower than the general market return

Hold – The fundamentals/valuations of the subject company are neither improving nor deteriorating and the investment return is expected to be in line with the general market return

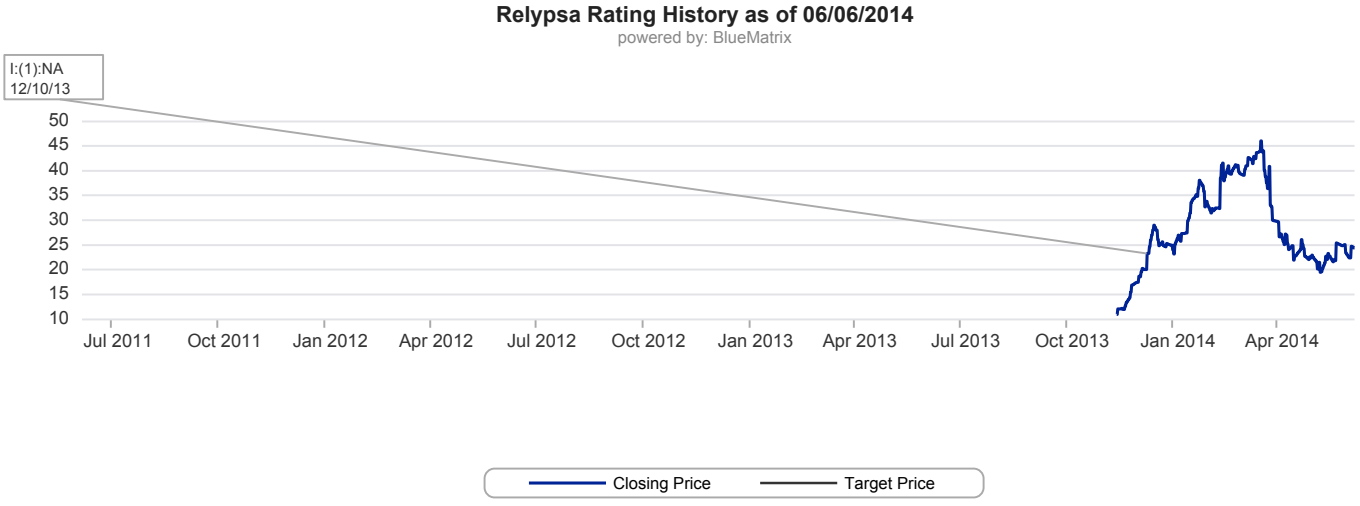
Cowen And Company Rating Definitions

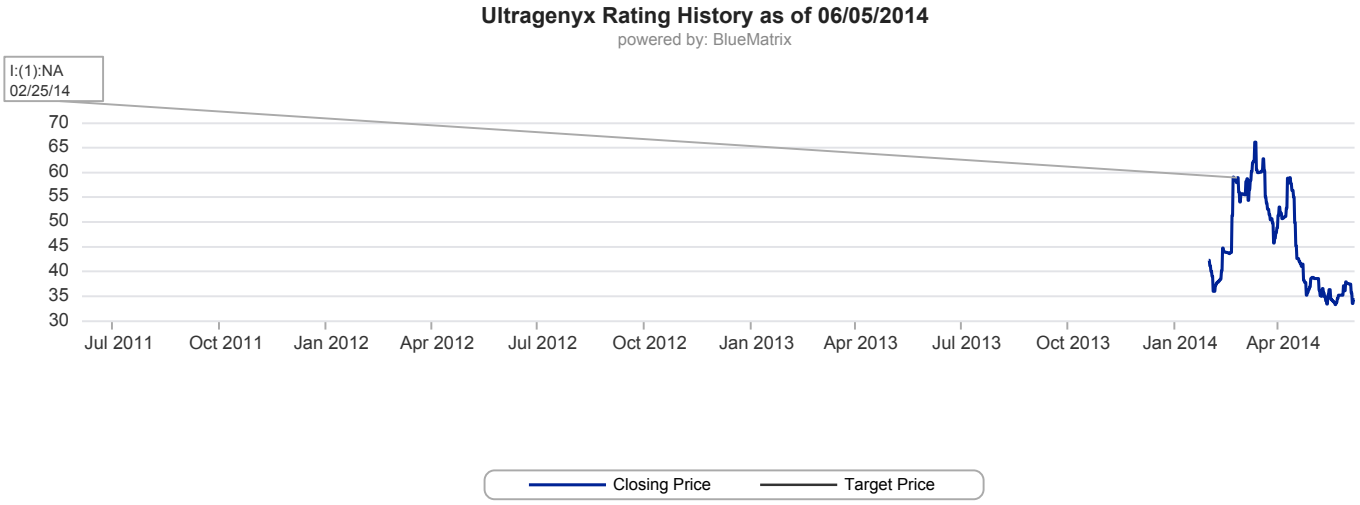
Distribution of Ratings/Investment Banking Services (IB) as of 03/31/14

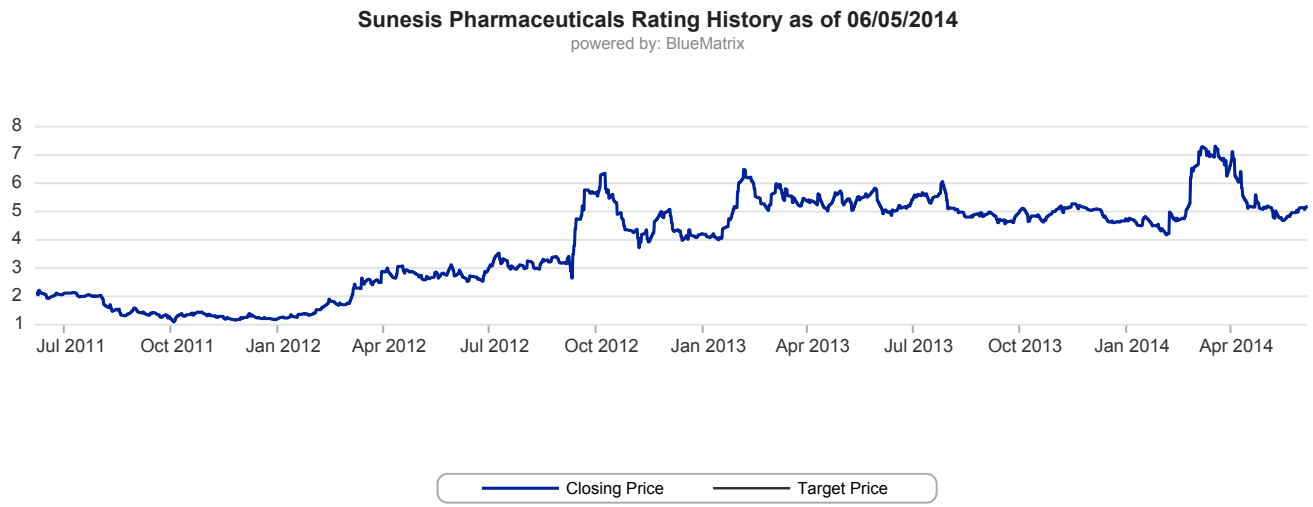
Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	407	57.08%	85	20.88%
Hold (b)	288	40.39%	8	2.78%
Sell (c)	18	2.52%	1	5.56%

(a) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's rating definitions. (b) Corresponds to "Market Perform" as defined in Cowen and Company, LLC's ratings definitions. (c) Corresponds to "Underperform" as defined in Cowen and Company, LLC's ratings definitions.

Note: "Buy", "Hold" and "Sell" are not terms that Cowen and Company, LLC uses in its ratings system and should not be construed as investment options. Rather, these ratings terms are used illustratively to comply with FINRA and NYSE regulations.







Rating Change - 2/21/2006 - Outperform Rating

Legend for Price Chart:

I = Initiation | 1 = Outperform | 2 = Market Perform | 3 = Underperform | UR = Price Target Under Review | T = Terminated Coverage | $xx = Price Target | NA = Not Available | S=Suspended

Points Of Contact

Analyst Profiles

Eric Schmidt, Ph.D.
New York
646.562.1345
eric.schmidt@cowen.com

Eric Schmidt is a senior analyst covering the biotechnology sector. He joined Cowen in 1998, having previously worked at UBS Securities.

Cristina Ghenoiu, Ph.D.
New York
646.562.1401
cristina.ghenoiu@cowen.com

Cristina Ghenoiu is an associate covering biotech. Before joining Cowen in 2013, she was a research scientist at Rockefeller University.

Reaching Cowen

Main U.S. Locations

New York
599 Lexington Avenue
New York, NY 10022
646.562.1000
800.221.5616

Boston
Two International Place
Boston, MA 02110
617.946.3700
800.343.7068

Cleveland
20006 Detroit Road
Suite 100
Rocky River, OH 44116
440.331.3531

San Francisco
555 California Street, 5th Floor
San Francisco, CA 94104
415.646.7200
800.858.9316

Atlanta
3399 Peachtree Road NE
Suite 417
Atlanta, GA 30326
866.544.7009

Chicago
181 West Madison Street
Suite 1925
Chicago, IL 60602
312.577.2240

Houston
600 Travis Street
Suite 1970
Houston, TX 77002
281.657.6800

International Locations

Cowen International Limited

London
1 Snowden Street - 11th Floor
London EC2A 2DQ
United Kingdom
44.20.7071.7500

Cowen and Company (Asia) Limited

Hong Kong
Suite 1401 Henley Building
No. 5 Queens Road Central
Central, Hong Kong
852 3752 2333