

Equity Research

October 2, 2015

Price: \$18.83 (10/1/2015)

Price Target: \$45.00

OUTPERFORM (1)

Ken Cacciatore

646.562.1305

ken.cacciatore@cowen.com

Sal Rais, M.D.

646.562.1420

sal.rais@cowen.com

Tyler Van Buren, M.Sc.

646.562.1338

tyler.vanburen@cowen.com

Key Data

Symbol [NASDAQ: CHRS](#)

Market Cap (MM) [\\$721.2](#)

Quick Take: Company Update

CHS-1701 Profile Appears Consistent, Reproducible And Approvable

The Cowen Insight

CHRS has 3 biosimilar products in development: (1) CHS-1420 (Humira); (2) CHS-0214 (Enbrel); and (3) CHS-1701, (Neulasta). Our \$45 target is based on conservative penetration into the RA & psoriasis markets for CHS-1420 and CHS-0214, with modest contribution from CHS-1701 (the basis of this note). With several disclosures expected over the next 6-12 months, significant value creation could occur.

CHS-1701 Demonstrates A Clear And Consistent Profile

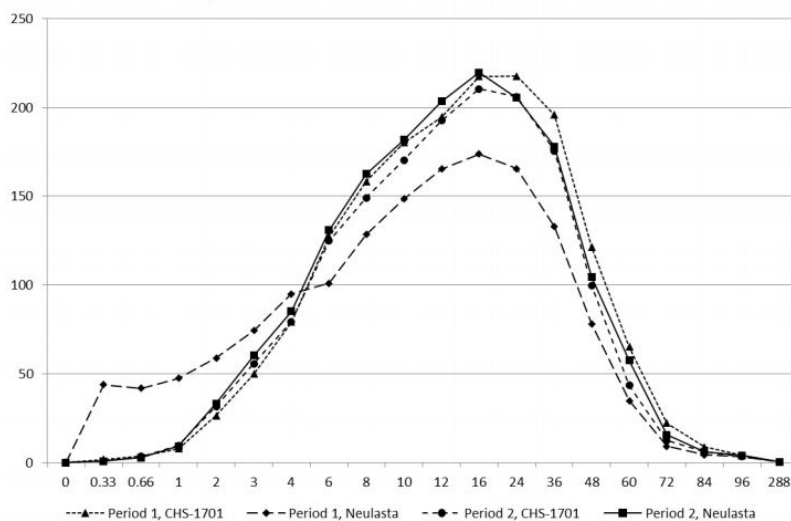
Last night Coherus announced the topline PK/PD study results for CHS-1701, the company's biosimilar of Amgen's Neulasta (pegfilgrastim). The bottom-line is that Coherus appears to have a highly consistent formulation of pegfilgrastim that matches the *historical* PK/PD profile of Neulasta. As we will explain within this note, we have italicized "historical" because one of the comparator arms of branded Neulasta in the study had results that were significantly different than the well-established historical profile of the product, as well as the second Neulasta comparator group, which did match the historical profile. This comparator arm anomaly should have no bearing on the key metric of the study, which was the successful and consistent replication of the PK/PD profile of CHS-1701 compared to a normalized profile of Neulasta. Stated clearly, one of the control arms of the study acted inconsistently, but that does not appear to be a concern of the FDA – especially in light of the CHS-1701 performance. Furthermore, with no neutralizing antibodies being identified during this PK/PD study, we now have greater confidence in the outcome of the ongoing CHS-1701 immunogenicity study (discussed in detail below). This study just recently completed enrollment, and if successful, could allow Coherus to potentially be first-to-market with a biosimilar Neulasta, especially given the ongoing litigation between Amgen and Apotex (also discussed below).

As for the background, recall, Coherus previously received guidance from the FDA regarding the regulatory requirements for CHS-1701, which included two clinical studies for approval: (1) A two-period single-dose PK/PD study in 116 healthy volunteers, and (2) A parallel group, two-dose immunogenicity study with 80 healthy volunteers in each group (CHS-1701 versus Neulasta). Regarding the PK/PD study, during the first period of the trial, subjects received either a single subcutaneous dose of 6mg CHS-1701 or 6mg Neulasta. After a 6-8 week washout, patients were then switched to receive a single dose of the other product during the second period of the study (CHS-1701 then Neulasta or vice versa). As for the data disclosed last night, regarding the PK assessment, CHS-1701 achieved bioequivalence to Neulasta for C_{max} , but did not achieve bioequivalence for Area Under the Curve (AUC). Interestingly, the reason for the "miss" appears to be due to the anomalous performance of the Neulasta control group during the first period of the study (as demonstrated in the graph below). Specifically, management indicated that the Neulasta PK profile seen during the first period was highly inconsistent with the well-established historical profile of the drug, which has been demonstrated in multiple studies by Amgen. The Neulasta PK profile during this first period was also highly

inconsistent with the PK profile during the second period of the study, which does match the well-established historical profile of the drug.

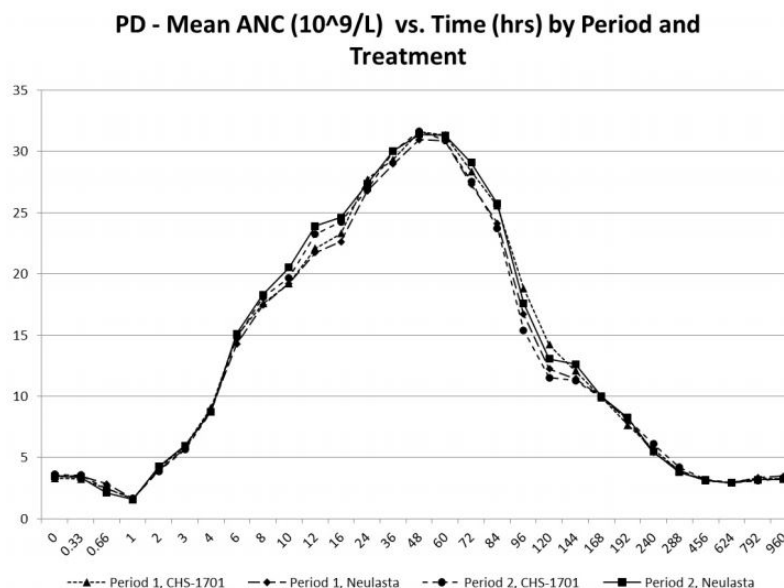
Most importantly, CHS-1701 was highly consistent during all phases of the study and achieved bioequivalence with Neulasta during the second period of the trial, which as we indicated above, was when the drug performed in accordance with its historical profile. Although it is unclear what caused the anomalous PK performance of Neulasta during the first period comparator group, given the consistency of CHS-1701 in both phases of the study, the exact cause is likely not meaningful and does not appear to be a concern of the FDA. Specifically, management indicated that the FDA has not recommended initiating a repeat study, which appears due to their comfort in their understanding of the well-established profile of Neulasta. Although we believe it will be unnecessary, if Coherus was asked to conduct another confirmatory PK/PD study, it would likely take roughly five months (from enrollment to data release) and cost approximately \$3.5-5.0MM. The bottom-line is, as we indicated above, that Coherus appears to have a highly consistent formulation of pegfilgrastim that matches the historical PK/PD profile of Neulasta. Furthermore, with no neutralizing antibodies being identified during this PK/PD study, we now have greater confidence in the outcome of the ongoing CHS-1701 immunogenicity study. This study just recently completed enrollment, and if successful, could allow Coherus to potentially be first-to-market with a biosimilar Neulasta, especially given the ongoing litigation between Amgen and Apotex.

**PK - Mean Plasma Concentration (ng/mL) vs. Time (hrs)
by Period and Treatment**



Source: Coherus

Regarding the PD assessment for CHS-1701, the biosimilar met both primary endpoints of (1) absolute neutrophil count (ANC) C_{max} and (2) absolute neutrophil count Area Under the Curve (AUC). The matched profile of CHS-1701 and Neulasta is clearly demonstrated in the graph below. This PD data provides further positive confirmation of the CHS-1701 profile.



Source: Coherus

Immunogenicity Study Is Ongoing

Recall that Coherus recently disclosed that it increased enrollment in the ongoing CHS-1701 immunogenicity study to ensure optimal powering. This study enrollment is now complete and the reason for the expansion is what appeared to be an increased aggregate anti-drug antibody rate in the overall study following a blinded preliminary interim look. Of note, the study is still completely blinded, so it is unclear at this point if the CHS-1701 arm, or the Neulasta control arm, is driving the higher aggregate antibody rate observed so far. Although alterations to a study need to be properly vetted, we believe that this increased enrollment and the suggestion of a higher antibody rate are explainable, and at this point, not overly concerning. We would note that the historical rate of anti-drug antibodies in Neulasta is approximately 3-5%, however, the company believed that the rate in the immunogenicity study would be on the higher end of that range because the latest-generation assays being utilized for detecting antibodies are more sensitive. Nonetheless, in order to pursue the most ethical trial design to minimize the number of healthy volunteers exposed to the Neulasta/CHS-1701 side effects, Coherus powered the study assuming a roughly 5% antibody rate (i.e., initially enrolled a minimum threshold of patients). To compensate for what would likely and potentially occur, Coherus designed into the study a pre-specified allowance of a preliminary blinded look at the aggregate antibody rates, and also included a corresponding pre-specified option to increase the enrollment if higher antibody rates were observed. And indeed, based on this interim analysis, Coherus found that the aggregate rate of antibodies being observed was 1-2% above the historical Neulasta rates (so approximately 6-7%), and in order to ensure optimal powering, decided to increase the enrollment. To reiterate, this was all pre-specified (the interim look and the ability to increase enrollment), which should provide comfort that management was pursuing the most ethical design given the utilization of healthy volunteers. Management indicated that the additional enrollment will place the immunogenicity data disclosure and NDA filing into Q1:2016, which is essentially on track with previous guidance. Although we now must await the final disclosure of the full data set, at this point management's explanation appears sound and the trial design very reasonable and appropriate. We continue to believe that CHS-1701 remains very much on track.

Importantly, regarding the recently issued 8,952,138 manufacturing patent, we do not believe this will pose a legal impediment to Coherus. For background, recall that

Apotex submitted the first (and thus far only) application for approval of biosimilar Neulasta to the FDA last year and the application is believed to have an FDA action date in the fall. Amgen and Apotex have engaged in the patent exchange provisions detailed under the Biologic Price Competition and Innovation Act (BPCIA), but have failed to resolve their differences (which is unsurprising to us). Our colleague Eric Schmidt and the Cowen Biotechnology Team indicate a court document in Amgen vs. Apotex (found [here](#)) describes that Amgen continues to assert two patents against Apotex. U.S. patent 5,824,784 was previously known to us, and expires October 20, 2015. U.S. patent 8,952,138 is a new patent, issued in February 2015, that is valid until 2030 (a copy can be found [here](#)). It covers a method for manufacturing cysteine-containing proteins expressed in non-mammalian cells at high concentrations. Amgen has asked the courts for an injunction to delay the launch of biosimilar Neulasta until 180-days after FDA approval as the Federal Circuit recently ruled that a biosimilar sponsor may only give its 180-day notice once an application has been approved. In theory, this would delay an Apotex biosimilar Neulasta launch until at a minimum the spring of 2016. A court case to rule on the merits of Amgen's patents is scheduled for July 2016. If the courts rule that Amgen's new '138 patent is valid and infringed, the launch of a biosimilar Neulasta via Apotex may be delayed much further.

While the strength of this new patent is still not clear, because Amgen and Apotex have engaged in the patent exchange process wherein Apotex supplied Amgen with a copy of its BLA filing, Amgen likely knows the conditions under which Apotex is manufacturing its biosimilar Neulasta and likely has good reason to believe that Apotex's process infringes the written claims of the '138 patent. With a court date scheduled for July 2016, the question may become whether Apotex would launch at risk. Given the size of the Neulasta franchise (nearly \$4B in the U.S. sales) and the risk of treble damages were Apotex found to be in willful infringement of valid manufacturing claims, we suspect an at-risk launch is unlikely. We also note that Amgen has asked the courts for an injunction to prevent any launch until after the claims of the '138 patent are litigated. Hence, we believe that the '138 patent might at a minimum delay launch of a biosimilar Neulasta until an H2:16 court ruling. Assuming Amgen were to prevail in courts, Neulasta biosimilars might be delayed beyond H2:16.

As this patent issue relates to Coherus, during the update call, management indicated that the manufacturing method described in the '138 patent is not utilized for the production of CHS-1701. This would suggest that if Apotex's Neulasta biosimilar does in fact infringe the '138 patent, that CHS-1701 could potentially be the first Neulasta biosimilar approved and launched in the U.S., as it would appear that Coherus can circumvent it. This potential first-mover advantage was also aided by the guidance that Coherus received from the FDA that it will not need to conduct Phase III efficacy studies for CHS-1701 in patients with cancer due to the following reasons: (1) pegfilgrastim is a relatively simple molecule to characterize compared to other proteins such as monoclonal antibodies (i.e., smaller molecular weight, no glycosylation, straightforward pegylation, etc.); (2) treatment with the G-CSF analog is on an acute not chronic basis; and finally (3) there is a clear rapid efficacy marker, which is an increase in neutrophil counts that can be observed in both healthy patients and those with cancer. While these three attributes (easier ability to characterize, rapid and measurable effects, acute use versus chronic) are not applicable for all biosimilars, the Agency's willingness to approach each candidate with a degree of flexibility is encouraging for potential current and future targets. Management is in the early stages of formalizing its commercialization and reimbursement strategy, which is also encouraging. And to reiterate, Coherus' strategy to formulate and manufacture outside of the known patent estate could (and should) yield significant value as it will likely provide a much clearer legal pathway.

Regarding CHS-1420 (biosimilar Humira) – the company's key asset – Coherus continues to make stable progress. Recall that after receiving feedback from the Agency, Coherus has decided to conduct its pivotal Phase III program in plaque psoriasis. Specific for the U.S., the efficacy study will require a 16 week assessment with a PASI 75 endpoint (75% improvement in the Psoriasis Area and Severity Index score) while for the EMA, the regulators have suggested a 12 week assessment with a mean improvement in PASI endpoint. The study was initiated in August 2015. Additionally, the Company will also initiate a PK bioequivalence bridging study toward the end of H1:2016 using Phase III drug material. The BLA for CHS-1420 is expected to be filed in H2:2016 and we continue to remain encouraged by the straightforward dialogue and clinical guidance that Coherus has received from both the FDA and EMA for this key program.

Finally, regarding CHS-0214 (biosimilar Enbrel partnered with Baxalta and Daiichi Sankyo) enrollment for both the RA and psoriasis Phase III studies was completed in May 2015, for which Coherus received a \$35MM milestone payment from Baxalta. Top-line data for the psoriasis study is expected in Q4:2015 with data from the RA study expected in Q1:2016. CHS-0214 remains on track for regulatory filings in the EU and Japan in mid-2016. The bottom line is that Coherus continues to make significant progress with its biosimilars pipeline and several disclosures are expected over the next 6-12 months that could generate significant value for shareholders.

Coherus Is A Leader In What Should Be A Significant Biosimilars Market

By 2017, we estimate the WW sales of Humira for the rheumatoid arthritis (RA) and psoriasis indications alone will be approximately \$10B. For Enbrel, Amgen has U.S. patent protection until 2029 in the U.S., but we estimate the 2017 ex-U.S. sales will still be \$3.2B for just the RA and psoriasis indications. Finally, Neulasta WW sales are expected to be roughly \$4.4B by 2017. Put simply, Coherus is currently developing three lead biosimilar products with an estimated total addressable market of \$18B by 2017. And the Company's impressive development platform is easily transferable to a long list of additional biosimilar opportunities. From a clinician, patient, and overall health care system (government and commercial payors) perspective, there is an escalating, in fact we believe desperate, need for effective and therapeutically equivalent low-cost alternatives. We believe Coherus will be at the forefront of alleviating the massive cost pressures via what should be a successful development of its biosimilar products.

Valuation Remains Attractive Here

Our base-case valuation assumes U.S. approval for CHS-1420 (Humira) in 2017, and peak sales via direct commercialization by Coherus eventually reaching approximately \$1B, assuming a 3% penetration of the U.S. RA and psoriasis markets by 2022. We also assume ex-U.S. approvals of CHS-1420 in 2018 with peak royalty revenues of \$190MM+. For CHS-0214 (Enbrel), we assume ex-U.S. approvals in 2017 with peak royalty revenues of \$200MM+. Finally, we assume a 2017 U.S. approval for CHS-1701 (Neulasta) with peak sales via direct marketing by Coherus of \$260MM+. We also assume ex-U.S. approval of CHS-1701 in 2018 with peak royalty revenues of \$30MM+. We would note, our valuation does not attribute any value to the potential additional indications for CHS-1420 and CHS-0214 that are currently found in the labels for Humira and Enbrel. Our industry checks continue to suggest that physicians are willing to use biosimilars and that managed care will clearly pressure for adoption. As a result, our current assumptions may prove to be conservative. We would note, our valuation does not attribute any value to the potential additional indications for CHS-1420 and CHS-0214 that are currently found in the labels for Humira and Enbrel. The broader utilization could garner significant upside to our base case \$45 valuation

since the RA and psoriasis indications only make up 55-60% of Humira's current U.S. sales.

Valuation Methodology And Risks

Valuation Methodology

Pharmaceuticals/Specialty

For our valuation methodology, we arrive at fair value utilizing a discounted cash flow (DCF) approach to derive our 12-month price target.

Investment Risks

Pharmaceuticals/Specialty

Risks include: (1) growing competitive dynamics in the specialty pharmaceuticals space; (2) the ability of management to execute on external growth by successfully acquiring new strategic, accretive products; (3) the ability to grow organically and keep the product pipeline robust; (4) potential regulatory delays, rejections, or failures of pipeline products; (5) economic sensitivity of any self-pay products or weakening consumer demand; (6) domestic or international pricing pressures for marketed products; and (7) failure to execute on new product launches.

Risks To The Price Target

Coherus is a development-stage biosimilar company and while the strategy appears to be risk-mitigated from a clinical efficacy perspective, regulatory and legal hurdles could negatively affect the company's share price.

Addendum

Stocks Mentioned in Important Disclosures

Ticker	Company Name
CHRS	Coherus BioSciences

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.

Important Disclosures

Cowen and Company, LLC and/or its affiliates make a market in the stock of Coherus BioSciences securities.

Coherus BioSciences has been client(s) of Cowen and Company, LLC in the past 12 months.

Coherus BioSciences 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 IB services.

Cowen and Company, LLC and/or its affiliates received in the past 12 months compensation for investment banking services from Coherus BioSciences.

Cowen and Company, LLC and/or its affiliates managed or co-managed a public offering of Coherus BioSciences within the past twelve months.

Cowen and Company, LLC compensates research analysts for activities and services intended to benefit the firm's investor clients. Individual compensation determinations for research analysts, including the author(s) of this report, are based on a variety of factors, including the overall profitability of the firm and the total revenue derived from all sources, including revenues from investment banking. Cowen and Company, LLC does not compensate research analysts based on specific investment banking transactions.

Disclaimer

This research is for our clients only. Our research is disseminated primarily electronically and, in some cases, in printed form. Research distributed electronically is available simultaneously to all Cowen and Company, LLC clients. All published research can be obtained on the Firm's client website, <https://cowenlibrary.bluematrix.com/client/library.jsp>.

Further information on any of the above securities may be obtained from our offices. This report is published solely for information purposes, and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state where such an offer or solicitation would be illegal. Other than disclosures relating to Cowen and Company, LLC, the information herein is based on sources we believe to be reliable but is not guaranteed by us and does not purport to be a complete statement or summary of the available data. Any opinions expressed herein are statements of our judgment on this date and are subject to change without notice.

For important disclosures regarding the companies that are the subject of this research report, please contact Compliance Department, Cowen and Company, LLC, 599 Lexington Avenue, 20th Floor, New York, NY 10022. In addition, the same important disclosures, with the exception of the valuation methods and risks, are available on the Firm's disclosure website at <https://cowen.bluematrix.com/sellside/Disclosures.action>.

Price Targets: Cowen and Company, LLC assigns price targets on all covered companies unless noted otherwise. The price target for an issuer's stock represents the value that the analyst reasonably expects the stock to reach over a performance period of twelve months. The price targets in this report should be considered in the context of all prior published Cowen and Company, LLC research reports (including the disclosures in any such report or on the Firm's disclosure website), which may or may not include price targets, as well as developments relating to the issuer, its industry and the financial markets. For price target valuation methodology and risks associated with the achievement of any given price target, please see the analyst's research report publishing such targets.

Notice to UK Investors: This publication is produced by Cowen and Company, LLC which is regulated in the United States by FINRA. It is to be communicated only to persons of a kind described in Articles 19 and 49 of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005. It must not be further transmitted to any other person without our consent.

Copyright, User Agreement and other general information related to this report

© 2015 Cowen and Company, LLC. Member NYSE, FINRA and SIPC. All rights reserved. This research report is prepared for the exclusive use of Cowen clients and may not be reproduced, displayed, modified, distributed, transmitted or disclosed, in whole or in part, or in any form or manner, to others outside your organization without the express prior written consent of Cowen. Cowen research reports are distributed simultaneously to all clients eligible to receive such research reports. Any unauthorized use or disclosure is prohibited. Receipt and/or review of this research constitutes your agreement not to reproduce, display, modify, distribute, transmit, or disclose to others outside your organization the contents, opinions, conclusion, or information contained in this report (including any investment recommendations, estimates or price targets). All Cowen trademarks displayed in this report are owned by Cowen and may not be used without its prior written consent.

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

COWEN AND COMPANY RATING DEFINITIONS

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 09/30/15

Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	492	59.49%	118	23.98%
Hold (b)	317	38.33%	11	3.47%
Sell (c)	18	2.18%	0	0.00%

(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.

Coherus BioSciences Rating History as of 10/01/2015

powered by: BlueMatrix



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

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

One Maritime Plaza, 9th Floor
San Francisco, CA 94111
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 3135
Chicago, IL 60602
312.577.2240

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

