

EQUITY RESEARCH

February 10, 2021

■ **Biotechnology**

Phil Nadeau, Ph.D.

646 562 1336
phil.nadeau@cowen.com

Kenneth Atkins, Ph.D.

646 562 1410
kenneth.atkins@cowen.com

Ernesto Rodriguez-Dumont, M.D.

646 562 1347
Ernesto.RodriguezDumont@cowen.com

QUICK TAKE: INDUSTRY UPDATE

GILD AND GLPG DISCONTINUE ZIRITAXESTAT'S ISABELA PH. IIIS IN IPF

THE COWEN INSIGHT

GILD/GLPG announced that ziritaxestat's Ph. III ISABELA trials in IPF are being discontinued. With mixed Ph. II results, expectations for ziritaxestat were relatively low, though admittedly a determination of negative benefit-risk at a routine IDMC meeting is surprising. Our GILD and GLPG models contain no revenue assumptions for ziritaxestat. We remain at Outperform on GILD and GLPG.

Our Take: Ziritaxestat's Demise In Not Overly Surprising, Though How It Came About Is Unexpected

The discontinuation of the ISABELA trials by GILD/GLPG is a disappointing outcome, but not an entirely surprising one. As Ziritaxestat was moved into Phase III on somewhat mixed results from the Ph. II FLORA trial, many had worried that the upcoming futility analysis in the ISABELA program would yield a negative outcome and that the Phase III trials would not progress to completion. However, few anticipated that a routine DSMB review of the unblinded data would yield a determination of negative benefit-risk. Thus, the reason for ziritaxestat's demise is surprising, even if the outcome is not particularly.

Neither our GILD nor our GLPG model contain any assumptions for revenue from ziritaxestat, as we were not convinced that the ISABELA trials would succeed. Galapagos had based the advancement of ziritaxestat upon the data from the FLORA trial. The trial had yielded an improvement of 95mL in FVC for ziritaxestat vs. placebo at week 12. However, the result was not statistically significant, was due to a more rapid than anticipated decline in placebo FVC, included only 17 patients, was assessed over short follow-up, and there were a number of patients missing from the FVC analyses. An additional risk factor for the ISABELA trials was the fact that ziritaxestat had never previously been studied on top of pirfenidone or nintedanib.

That being said, this is yet another disappointment in a string of them from the GLPG/GILD collaboration, and some weakness in the stocks is understandable.

We remain at Outperform on GILD and GLPG. Today's news has no impact on our GILD revenue projections, and our DCF-based P.T. remains \$75.

After this morning's weakness GLPG is trading at close to cash per share. However, Galapagos maintains full rights to approved product Jyseleca in the EU, and has a pipeline that includes GLPG1205 (Phase II for IPF) and GLPG3970 (Toledo, Phase II in inflammatory diseases). Trading with a modest enterprise value, we think GLPG shares are positioned for meaningful outperformance should Jyseleca's EU launch or any of the pipeline programs be successful.

The News: This morning, Galapagos and Gilead announced that the ISABELA Phase III clinical studies evaluating ziritaxestat for the treatment of idiopathic pulmonary fibrosis (IPF) are being discontinued.

The decision stems from a recommendation by the Independent Data Monitoring Committee (IDMC), following a regular review of the unblinded data. Upon review of the data, the IDMC concluded that ziritaxestat's benefit:risk profile did not support the continuation of the studies. All clinical trials with ziritaxestat, including the long-term extension of the Phase IIa NOVESA trial in systemic sclerosis, will be discontinued. The decision came in advance of the anticipated H1:21 futility analysis in the ISABELA program.

Gilead Sciences (GILD; \$67.36, 2/10/2021 intraday price)

Galapagos NV (ADR) (GLPG; \$89.05 2/10/21 intraday price)



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.

ADDENDUM

Stocks Mentioned In Important Disclosures

Ticker	Company Name
GLPG	Galapagos NV (ADR)
GILD	Gilead Sciences

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 Gilead Sciences and Galapagos NV (ADR) securities.

Cowen and Company, LLC acted as Financial Advisor to Gilead Sciences, Inc. regarding the 10-year partnership with Arcus Biosciences, Inc. ("Arcus") to co-develop and co-commercialize current and future therapeutic product candidates in Arcus' pipeline, that closed on July 13, 2020.

On 7/16/2020, Gilead Sciences announced entering an asset purchase agreement with Kronos Bio. Cowen acted as Financial Advisor to Gilead Sciences.

On 7/21/2020, Gilead Sciences, Inc. announced it will invest \$300 Million to acquire a 49.9 percent equity interest in Tizona Therapeutics, Inc. Cowen is acting as Financial Advisor to Gilead Sciences, Inc. The transaction closed on August 25, 2020.

On 10/23/2020, Gilead Sciences, Inc. announced it completed the acquisition of Immunomedics, Inc. Cowen and Company, LLC acted as financial advisor to Immunomedics, Inc.

Cowen and Company, LLC received compensation for investment banking services from Gilead Sciences in the past 12 months.

Cowen and Company, LLC and/or its affiliates expect to receive, or intend to seek, compensation for investment banking services in the next 3 months from Gilead Sciences.

Gilead Sciences is or has been in the past 12 months a client of Cowen and Company, LLC; Cowen and Company, LLC has provided or is providing investment banking services during the past 12 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, sales and trading or principal trading revenues. Cowen and Company, LLC does not compensate research analysts based on specific investment banking transactions or specific sales and trading or principal trading revenues.

Disclaimer

Our research reports are simultaneously available to all clients on our client website. Research reports are for our clients only. Not all research reports are disseminated, e-mailed or made available to third-party aggregators. Cowen and Company, LLC is not responsible for the redistribution of research by third party aggregators. Selected research reports are available in printed form in addition to an electronic form. All published research reports can be obtained on the firm's client website, <https://cowenlibrary.bluematrix.com/client/library.jsp>.

The information, opinions, estimates and forecasts are as of the date of this report and subject to change without prior notification. We seek to update our research as appropriate, but various regulations may prevent us from doing so. Research reports are published at irregular intervals as appropriate in the analyst's judgement.

Further information on subject securities may be obtained from our offices. This research 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. The opinions and recommendations herein do not take into account individual client circumstances, objectives or needs and are not intended as recommendations of investment strategy. The recipients of this report must make their own independent decisions regarding any securities subject to this research report. In some cases, securities and other financial instruments may be difficult to value or sell and reliable information about the value or risks related to the security or financial instrument may be difficult to obtain. To the extent that this report discusses any legal proceedings or issues, it has not been prepared to express or intended to express any legal conclusion, opinion or advice. Our salespeople, traders and other professionals may provide oral or written market commentary or trading strategies to our clients that reflect opinions that are contrary to the opinions expressed in our research. Our principal trading area and investing businesses may make investment decisions that are inconsistent with recommendations or views expressed in our research. Cowen and Company, LLC maintains physical, electronic and procedural information barriers to address the flow of information between and among departments within Cowen and Company, LLC in order to prevent and avoid conflicts of interest with respect to analyst recommendations.

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>.

Equity Research Price Targets: Cowen and Company, LLC assigns price targets on all companies covered in equity research unless noted otherwise. The equity research 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. Any price targets in equity securities in this report should be considered in the context of all prior published Cowen and Company, LLC equity research reports (including the disclosures in any such equity report or on the Firm's disclosure website), which may or may not include equity research price targets, as well as developments relating to the issuer, its industry and the financial markets. For equity research price target valuation methodology and risks associated with the achievement of any given equity research price target, please see the analyst's equity research report publishing such targets.

Cowen Cross-Asset Research: Due to the nature of the fixed income market, the issuers or debt securities of the issuers discussed in "Cowen Cross-Asset Research" reports do not assign ratings and price targets and may not be continuously followed. Accordingly, investors must regard such branded reports as providing stand-alone analysis and reflecting the analyst's opinion as of the date of the report and should not expect continuing analysis or additional reports relating to such issuers or debt securities of the issuers.

From time to time "Cowen Cross-Asset Research" analysts provide investment recommendations on securities that are the subject of this report. These recommendations are intended only as of the time and date of publication and only within the parameters specified in each individual report. "Cowen Cross-Asset Research" investment recommendations are made strictly on a case-by-case basis, and no recommendation is provided as part of an overarching rating system or other set of consistently applied benchmarks. The views expressed in "Cross-Asset Research" report may differ from the views offered in the firm's equity research reports prepared for our clients.

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.

Notice to European Union Investors: Individuals producing recommendations are required to obtain certain licenses by the Financial Regulatory Authority (FINRA). You can review the author's current licensing status and history, employment history and, if any, reported regulatory, customer dispute, criminal and other matters via "Brokercheck by FINRA" at <http://brokercheck.finra.org/>. An individual's licensing status with FINRA should not be construed as an endorsement by FINRA. General biographical information is also available for each Research Analyst at www.cowen.com.

Additionally, the complete preceding 12-month recommendations history related to recommendation in this research report is available at [https://cowen.bluematrix.com/sellside/ Disclosures.action](https://cowen.bluematrix.com/sellside/Disclosures.action)

The recommendation contained in this report was produced at February 10, 2021, 11:52 ET. and disseminated at February 10, 2021, 11:52 ET.

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

© 2021 Cowen and Company, LLC. All rights reserved. Member NYSE, FINRA and SIPC. 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. 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 1010 **Boston** 617 946 3700 **San Francisco** 415 646 7200 **Chicago** 312 577 2240 **Cleveland** 440 331 3531 **Atlanta** 866 544 7009 **Stamford** 646 616 3000 **Washington, D.C.** 202 868 5300 **London** (affiliate) 44 207 071 7500

COWEN AND COMPANY EQUITY RESEARCH RATING DEFINITIONS

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 Equity Research Rating Distribution

Distribution of Ratings/Investment Banking Services (IB) as of 12/31/20

Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	538	67.17%	156	29.00%
Hold (b)	258	32.21%	19	7.36%
Sell (c)	5	0.62%	0	0.00%

(a) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's equity research rating definitions. (b) Corresponds to "Market Perform" as defined in Cowen and Company, LLC's equity research ratings definitions. (c) Corresponds to "Underperform" as defined in Cowen and Company, LLC's equity research ratings definitions. Cowen and Company Equity Research Rating Distribution Table does not include any company for which the equity research rating is currently suspended or any debt security followed by Cowen Credit Research and Trading.

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 regulation.

Gilead Sciences Rating History as of 02/09/2021

powered by: BlueMatrix



Galapagos NV (ADR) Rating History as of 02/09/2021

powered by: BlueMatrix



Initiated Coverage - 06/08/2015 - Rating Outperform

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 1010
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

3424 Peachtree Road NE
Suite 2200
Atlanta, GA 30326
866 544 7009

Chicago

181 West Madison Street
Suite 3135
Chicago, IL 60602
312 577 2240

Stamford

262 Harbor Drive
Stamford, CT 06902
646 616 3000

Washington, D.C.

2900 K Street, NW
Suite 520
Washington, DC 20007
202 868 5300

International Location

Cowen International Limited**London**

1 Snowden Street - 11th Floor
London EC2A 2DQ
United Kingdom
44 20 7071 7500

