William Blair

April 10, 2025

Max Smock, CFA +1 312 364 8336
msmock@williamblair.com

Christine Rains, CFA +1 312 364 8217
crains@williamblair.com

Pharmaceutical Outsourcing & Services

FDA Announces Plan to Phase Out Animal Testing Requirement for Certain Drugs

What Happened?
On Thursday, April 10, the U.S. Food and Drug Administration (FDA) announced its plan to replace the animal testing requirement for the development of monoclonal antibody (mAb) therapies and other drugs with more effective, human-relevant methods, including advanced computer simulations and human-based lab models, which it collectively dubbed new approach methodologies (NAMs). Further, the agency noted that it will begin utilizing preexisting, real-world safety data from other regulatory-comparable countries where a target drug has already been studied in humans to help determine efficacy. According to the release, the agency believes these changes will lead to improved drug safety and animal welfare, lower R&D costs, and ultimately, reduced drug prices.

While the precise timeline for the elimination of the animal testing requirement is unclear, the FDA indicated that implementation of the phase-out will begin immediately for investigational new drug (IND) applications, where inclusion of NAMs data is encouraged, and highlighted its ultimate goal for the animal testing requirement to be reduced, refined, or potentially replaced. It appears that the details of the implementation process are still being ironed out, with the FDA announcing its plan for a public workshop on the topic later this year and noting its intent to launch a pilot program in the coming year to allow select mAb developers to use a primarily non-animal-based testing strategy, under close FDA consultation. Additionally, while the FDA is still in the process of updating its guidelines to allow consideration of data from these new methods, it alluded to the possibility of allowing companies that submit strong safety data from non-animal tests to benefit from a more streamlined application review process.

Our Take
Overall, we view Thursday's announcement largely as a statement of intent to assess and create regulations ensuring the safety and accuracy of utilizing non-animal-based alternatives in the preclinical development process, which previous administrations' had already been working toward (see FDA Modernization Act 2.0 from 2022 and FDA workshop from last October). That said, while the FDA Modernization Act 2.0 allowed for non-animal testing, the bill did not state any formal plans to refine, reduce, or completely replace animal testing over time. Even though we expect these changes to be rolled out gradually over time and believe drug developers will still want to do at least some animal testing, this is clearly going to be a major overhang for Charles River (CRL $99.95; Market Perform), which generates roughly 20% of its revenue from testing drugs in non-human primates (stock ended Thursday down 28%). From our coverage list, we believe this has the potential to be a major tailwind for Certara (CERT $10.51; Market Perform) and Simulations Plus (SLP $26.50; Outperform), both of which have preclinical models that can be used in place of, or in conjunction with, animal-based testing.

IMPORTANT DISCLOSURES

This report is available in electronic form to registered users via R*Docs™ at https://williamblairlibrary.bluematrix.com or www.williamblair.com.

Please contact us at +1 800 621 0687 or consult https://www.williamblair.com/equity-research/coverage for all disclosures.

Max Smock attests that 1) all of the views expressed in this research report accurately reflect his/her personal views about any and all of the securities and companies covered by this report, and 2) no part of his/her compensation was, is, or will be related, directly or indirectly, to the specific recommendations or views expressed by him/her in this report. We seek to update our research as appropriate. Other than certain periodical industry reports, the majority of reports are published at irregular intervals as deemed appropriate by the research analyst.

DOW JONES: 40608.40
S&P 500: 5456.90
NASDAQ: 17125.00

Additional information is available upon request.

Current Rating Distribution (as of April 10, 2025):

Coverage Universe	Percent	Inv. Banking Relationships *	Percent
Outperform (Buy)	71	Outperform (Buy)	10
Market Perform (Hold)	29	Market Perform (Hold)	1
Underperform (Sell)	1	Underperform (Sell)	0

*Percentage of companies in each rating category that are investment banking clients, defined as companies for which William Blair has received compensation for investment banking services within the past 12 months.

The compensation of the research analyst is based on a variety of factors, including performance of his or her stock recommendations; contributions to all of the firm's departments, including asset management, corporate finance, institutional sales, and retail brokerage; firm profitability; and competitive factors.

OTHER IMPORTANT DISCLOSURES

Stock ratings and valuation methodologies: William Blair & Company, L.L.C. uses a three-point system to rate stocks. Individual ratings reflect the expected performance of the stock relative to the broader market (generally the S&P 500, unless otherwise indicated) over the next 12 months. The assessment of expected performance is a function of near-, intermediate-, and long-term company fundamentals, industry outlook, confidence in earnings estimates, valuation (and our valuation methodology), and other factors. Outperform (O) - stock expected to outperform the broader market over the next 12 months; Market Perform (M) - stock expected to perform approximately in line with the broader market over the next 12 months; Underperform (U) - stock expected to underperform the broader market over the next 12 months; not rated (NR) - the stock is not currently rated. The valuation methodologies include (but are not limited to) price-to-earnings multiple (P/E), relative P/E (compared with the relevant market), P/E-to-growth-rate (PEG) ratio, market capitalization/revenue multiple, enterprise value/EBITDA ratio, discounted cash flow, and others. Stock ratings and valuation methodologies should not be used or relied upon as investment advice. Past performance is not necessarily a guide to future performance.

The ratings and valuation methodologies reflect the opinion of the individual analyst and are subject to change at any time.

Our salespeople, traders, and other professionals may provide oral or written market commentary, short-term trade ideas, or trading strategies-to our clients, prospective clients, and our trading desks-that are contrary to opinions expressed in this research report. Certain outstanding research reports may contain discussions or investment opinions relating to securities, financial instruments and/or issuers that are no longer current. Investing in securities involves risks. This report does not contain all the material information necessary for an investment decision. Always refer to the most recent report on a company or issuer. Our asset management and trading desks may make investment decisions that are inconsistent with recommendations or views expressed in this report. We will from time to time have long or short positions in, act as principal in, and buy or sell the securities referred to in this report. Our research is disseminated primarily electronically, and in some instances in printed form. Research is simultaneously available to all clients. This research report is for our clients only. No part of this material may be copied or duplicated in any form by any means or redistributed without the prior written consent of William Blair & Company, L.L.C.

This is not in any sense an offer or solicitation for the purchase or sale of a security or financial instrument.

The factual statements herein have been taken from sources we believe to be reliable, but such statements are made without any representation as to accuracy or completeness or otherwise, except with respect to any disclosures relative to William Blair or its research analysts. Opinions expressed are our own unless otherwise stated and are subject to change without notice. Prices shown are approximate.

This report or any portion hereof may not be copied, reprinted, sold, or redistributed or disclosed by the recipient to any third party, by content scraping or extraction, automated processing, or any other form or means, without the prior written consent of William Blair. Any unauthorized use is prohibited.

If the recipient received this research report pursuant to terms of service for, or a contract with William Blair for, the provision of research services for a separate fee, and in connection with the delivery of such research services we may be deemed to be acting as an investment adviser, then such investment adviser status relates, if at all, only to the recipient with whom we have contracted directly and does not extend beyond the delivery of this report (unless otherwise agreed specifically in writing). If such recipient uses these research services in connection with the sale or purchase of a security referred to herein, William Blair may act as principal for our own account or as riskless principal or agent for another party. William Blair is and continues to act solely as a broker-dealer in connection with the execution of any transactions, including transactions in any securities referred to herein.

For important disclosures, please visit our website at williamblair.com.

This material is distributed in the United Kingdom and the European Economic Area (EEA) by William Blair International, Ltd., authorised and regulated by the Financial Conduct Authority (FCA). William Blair International, Limited is a limited liability company registered in England and Wales with company number 03619027. This material is only directed and issued to persons regarded as Professional investors or equivalent in their home jurisdiction, or persons falling within articles 19 (5), 38, 47, and 49 of the Financial Services and Markets Act of 2000 (Financial Promotion) Order 2005 (all such persons being referred to as "relevant persons"). This document must not be acted on or relied on by persons who are not "relevant persons."

This report is being furnished in Brazil on a confidential basis and is addressed to the addressee personally, and for its sole benefit. This does not constitute an offer or solicitation for the purchase or sale of a security by any means that would constitute a public offering in Brazil under the regulations of the Brazilian Securities and Exchange Commission (*Comissão de Valores Mobiliários*) or an unauthorized distribution under Brazilian laws and regulations. The securities are authorized for trading on non-Brazilian securities markets, and this report and all the information herein is intended solely for professional investors (as defined by the applicable Brazilian regulation) who may only acquire these securities through a non-Brazilian account, with settlement outside Brazil in a non-Brazilian currency.

William Blair & Company, L.L.C. licenses and applies the SASB Materiality Map® and SICSTM in our work.

William Blair

Equity Research Directory

John Kreger, Partner Director of Research +1 312 364 8612
Kyle Harris, CFA, Partner Operations Manager +1 312 364 8230

Scott Hansen, Partner Associate Director of Research +1 212 245 6526

CONSUMER

Sharon Zackfia, CFA, Partner +1 312 364 5386
Group Head–Consumer
Lifestyle and Leisure Brands, Restaurants, Automotive/E-commerce

Jon Andersen, CFA, Partner +1 312 364 8697
Consumer Products

Phillip Blee, CPA +1 312 801 7874
Home and Outdoor, Automotive Parts and Services, Discount and Convenience

Dylan Carden +1 312 801 7857
E-commerce, Specialty Retail

ECONOMICS

Richard de Chazal, CFA +44 20 7868 4489

ENERGY AND SUSTAINABILITY

Jed Dorsheimer +1 617 235 7555
Group Head–Energy and Sustainability
Generation, Efficiency, Storage

Tim Mulrooney, Partner +1 312 364 8123
Sustainability Services

FINANCIAL SERVICES AND TECHNOLOGY

Adam Klauber, CFA, Partner +1 312 364 8232
Group Head–Financial Services and Technology
Financial Analytic Service Providers, Insurance Brokers, Property & Casualty Insurance

Andrew W. Jeffrey, CFA +1 415 796 6896
Fintech

Cristopher Kennedy, CFA +1 312 364 8596
Fintech, Specialty Finance

Jeff Schmitt +1 312 364 8106
Wealthtech, Wealth Management, Capital Markets Technology

GLOBAL SERVICES

Tim Mulrooney, Partner +1 312 364 8123
Group Head–Global Services
Commercial and Residential Services

Andrew Nicholas, CPA +1 312 364 8689
Consulting, HR Technology, Information Services

Trevor Romeo, CFA +1 312 801 7854
Staffing, Waste and Recycling

HEALTHCARE

Biotechnology

Matt Phipps, Ph.D., Partner +1 312 364 8602
Group Head–Biotechnology

Sami Corwin, Ph.D. +1 312 801 7783

Lachlan Hanbury-Brown +1 312 364 8125

Andy T. Hsieh, Ph.D., Partner +1 312 364 5051

Myles R. Minter, Ph.D., Partner +1 617 235 7534

Sarah Schram, Ph.D. +1 312 364 5464

Healthcare Technology and Services

Ryan S. Daniels, CFA, Partner +1 312 364 8418
Group Head–Healthcare Technology and Services
Healthcare Technology, Healthcare Services

Margaret Kaczor Andrew, CFA, Partner +1 312 364 8608
Medical Technology

Brandon Vazquez, CFA +1 212 237 2776
Dental, Animal Health, Medical Technology

Life Sciences

Matt Larew, Partner +1 312 801 7795
Life Science Tools, Bioprocessing, Healthcare Delivery

Andrew F. Brackmann, CFA +1 312 364 8776
Diagnostics

Max Smock, CFA +1 312 364 8336
Pharmaceutical Outsourcing and Services

INDUSTRIALS

Brian Drab, CFA, Partner +1 312 364 8280
Co-Group Head–Industrials
Advanced Manufacturing, Industrial Technology

Ryan Merkel, CFA , Partner +1 312 364 8603
Co-Group Head–Industrials
Building Products, Specialty Distribution

Louie DiPalma, CFA +1 312 364 5437
Aerospace and Defense, Smart Cities

Ross Sparenblek +1 312 364 8361
Diversified Industrials, Robotics, and Automation

TECHNOLOGY, MEDIA, AND COMMUNICATIONS

Jason Ader, CFA, Partner +1 617 235 7519
Co-Group Head–Technology, Media, and Communications
Infrastructure Software

Arjun Bhatia, Partner +1 312 364 5696
Co-Group Head–Technology, Media, and Communications
Software

Dylan Becker, CFA +1 312 364 8938
Software

Louie DiPalma, CFA +1 312 364 5437
Government Technology

Jonathan Ho, Partner +1 312 364 8276
Cybersecurity, Security Technology

Sebastien Naji +1 212 245 6508
Infrastructure Software, Semiconductor and Infrastructure Systems

Maggie Nolan, CPA, Partner +1 312 364 5090
IT Services

Jake Roberge +1 312 364 8056
Software

Ralph Schackart III, CFA, Partner +1 312 364 8753
Internet and Digital Media

Stephen Sheldon, CFA, CPA, Partner +1 312 364 5167
Vertical Technology – Real Estate, Education, Restaurant/Hospitality

EDITORIAL AND SUPERVISORY ANALYSTS

Steve Goldsmith, Head Editor and SA +1 312 364 8540

Audrey Majors, Editor and SA +1 312 364 8992

Beth Pekol Porto, Editor and SA +1 312 364 8924

Lisa Zurcher, Editor and SA +44 20 7868 4549