CELLO HEALTH BioConsulting

Previously Defined Health

THE ROCK JUST BELOW THE WATER: MARKET ACCESS RISK AND EARLY-STAGE BIOTECHS

Edward C. Saltzman, Executive Chairman

December 14, 2018

Presented in Collaboration with Real Endpoints

real endpoints

Distinguished Panelists

Moderator:

Ed Saltzman
Executive Chairman
Cello Health BioConsulting
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Panelists:

Jeffrey Berkowitz
CEO and Director
Real EndPoints

Roger Longman
Chairman
Real EndPoints

Dennis Purcell
Founder and Senior Advisor
Aisling Capital

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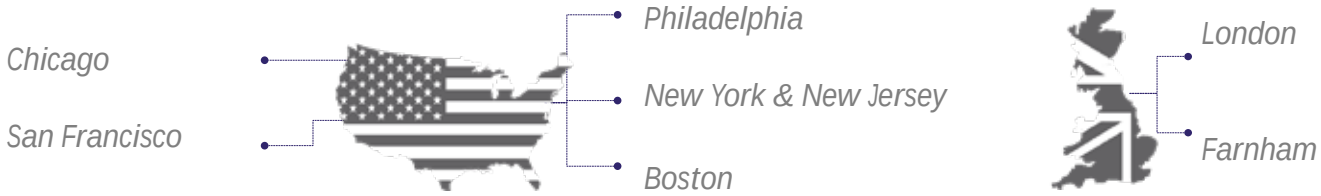
A worldwide team of more than 400 based in the US and UK

Offices in London, Farnham, New York, New Jersey, San Francisco, Chicago, Philadelphia and Boston



200 **Market Researchers,** Master Practitioners, Digital Specialists, Innovation leads, Field and Compliance

140 **Communication Specialists, Scientists & Creatives** including Client Service, Project Managers and Medical Writers

70+ **Consultants** with a blend of industry experts and consulting specialists

60+ **PhDs and MDs** providing a depth of understanding into cutting edge science

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Please join us for Cancer Progress 2019, and we hope to see you at these upcoming events!

CANCER PROGRESS

30TH Annual Cancer Progress Conference
May 7 – 8, 2019
Convene at 32 Old Slip, NYC
www.cancerprogressbyDH.com

Meet with us in SFO during JPM week!

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Access challenges are evolving faster than the capabilities to solve for them

Vertical and horizontal integration

CVS Health · aetna · Cigna · Express Scripts · WellCare · meridianRx · FedEx · Walgreens · amazon · Pill Pack

Government focus on Rx Cost and Transparency

American Patients First

The New York Times
Aug. 18, 2018
States Rush to Rein In Prescription Costs, and Drug Companies Fight Back

Forbes
Sep. 4, 2018, 08:40am
Medicaid To Introduce Value-Based Drug Pricing

Energized employers, providers

Berkshire Hathaway Inc. · amazon · JPMorgan Chase & Co.

CVS Health · ICER Institute for Clinical and Economic Review

CIVICA

Access-challenged, suboptimal launches

Dupixent (dupilumab) Injection 300mg

Zilretta triamcinolone acetonide extended-release injectable suspension 32 mg

Trulance (plecanatide)

Zejula niraparib capsules 100 mg

Sublocade (buprenorphine extended-release) injection for subcutaneous use 100mg-300mg

Tremfya (guselkumab)

TYMLOS (abaloparatide) injection

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Blinded Target Product Profile

Product X	
Description	Topical therapy for treatment of a rare genetic debilitating dermatologic disorder Daily, self-application of the ointment for up to 8 weeks
Mechanism of action	Undisclosed target: *acts by inhibition of an inflammation pathway*
Study Design	Double-blind, placebo-controlled, multi-center, randomized study; Product X as add-on to SOC treatment (Product X vs. placebo as add-on therapy)
Patient Population	Patients aged 10+ years; all disease severities
Efficacy Endpoints	**Primary Outcome:** % of patients with >40% lesion count reduction versus placebo at 4 weeks, with 12 week and 4 month follow-up
	Secondary Outcomes: % of patients with lesion count return to baseline at 12 week and 4 month follow-up versus placebo
Safety	No serious local or systemic AEs reported No discontinuations due to AEs

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What *should* be in a TPP? Among other elements…

- Unmet need from a payer's point of view (i.e., how many substitutable alternatives can be "step-edited" in front of candidate?)
- Indication severity (where does it fall on continuum between fatal and cosmetic)?
- Strength of evidence (trial comparator, structure)?
- Duration of treatment (chronic, short-term)?
- Medical benefit or pharmacy benefit?
- Credibility and ease-of-access of metrics for value-based contracts?
- Patient financial assistance program relative to competitors' programs?

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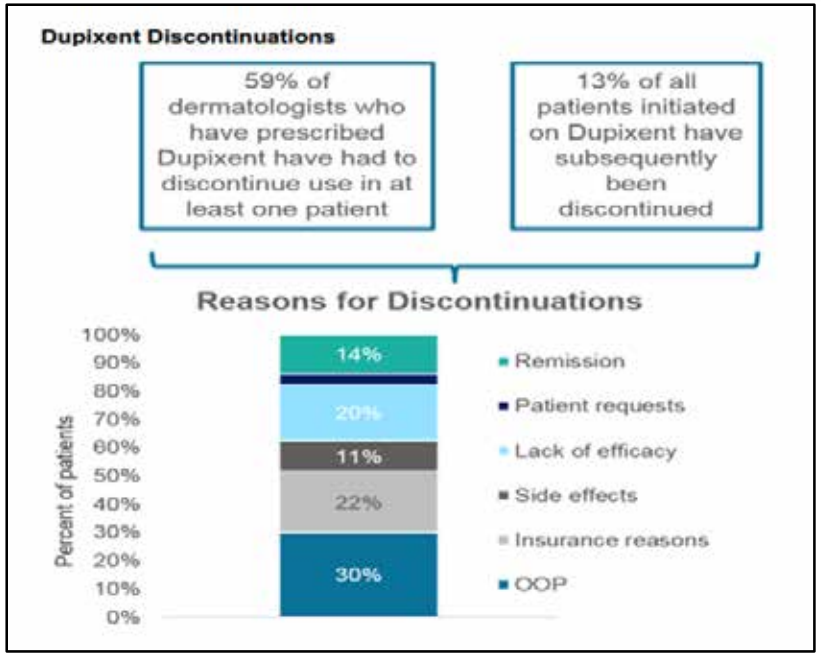
Dupixent for Atopic Dermatitis and Asthma

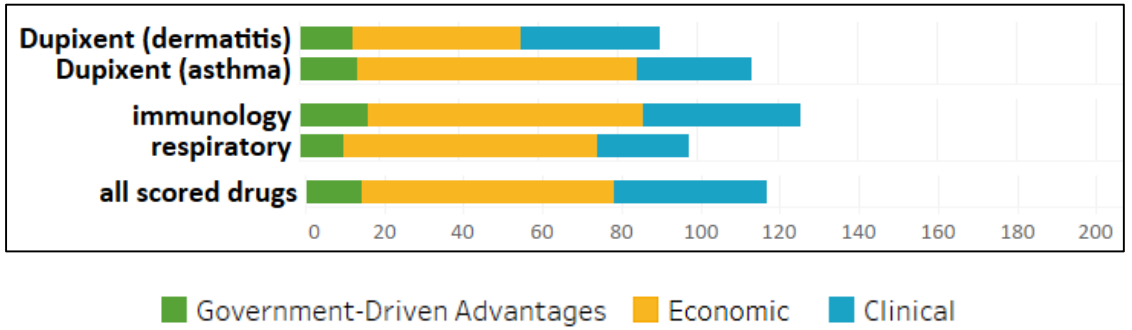
Dupixent

- Despite robust initial uptake, market access challenges remain for Dupixent, the first biologic approved for treatment of moderate/severe atopic dermatitis.
- Priced at $37,000 per year/patient, insurance coverage and out-of-pocket cost represent the reasons for >50% of all discontinuations in atopic dermatitis.
- FDA recently approved its use for asthma. Dupixent received broader label than its biologic competitors (Fasenra, Cinqair and Nucala), but given its price is slightly higher than these 3 biologics, payers are likely restrict its use and enforce access hurdles.
- Dupixent needs a 50% to 68% discount off its list price to meet ICER's cost effectiveness threshold of $150,000 per QALY.



Question: Of your Dupixent patients, how many have subsequently discontinued?

Dupixent Access Meter Scoring



Company: Regeneron

Indication 1: Atopic dermatitis (*approved 2017*)

Indication 2: Asthma (*approved October 2018*)

Source: Decision Resources Group; Indivior; Real Endpoints Access Meter

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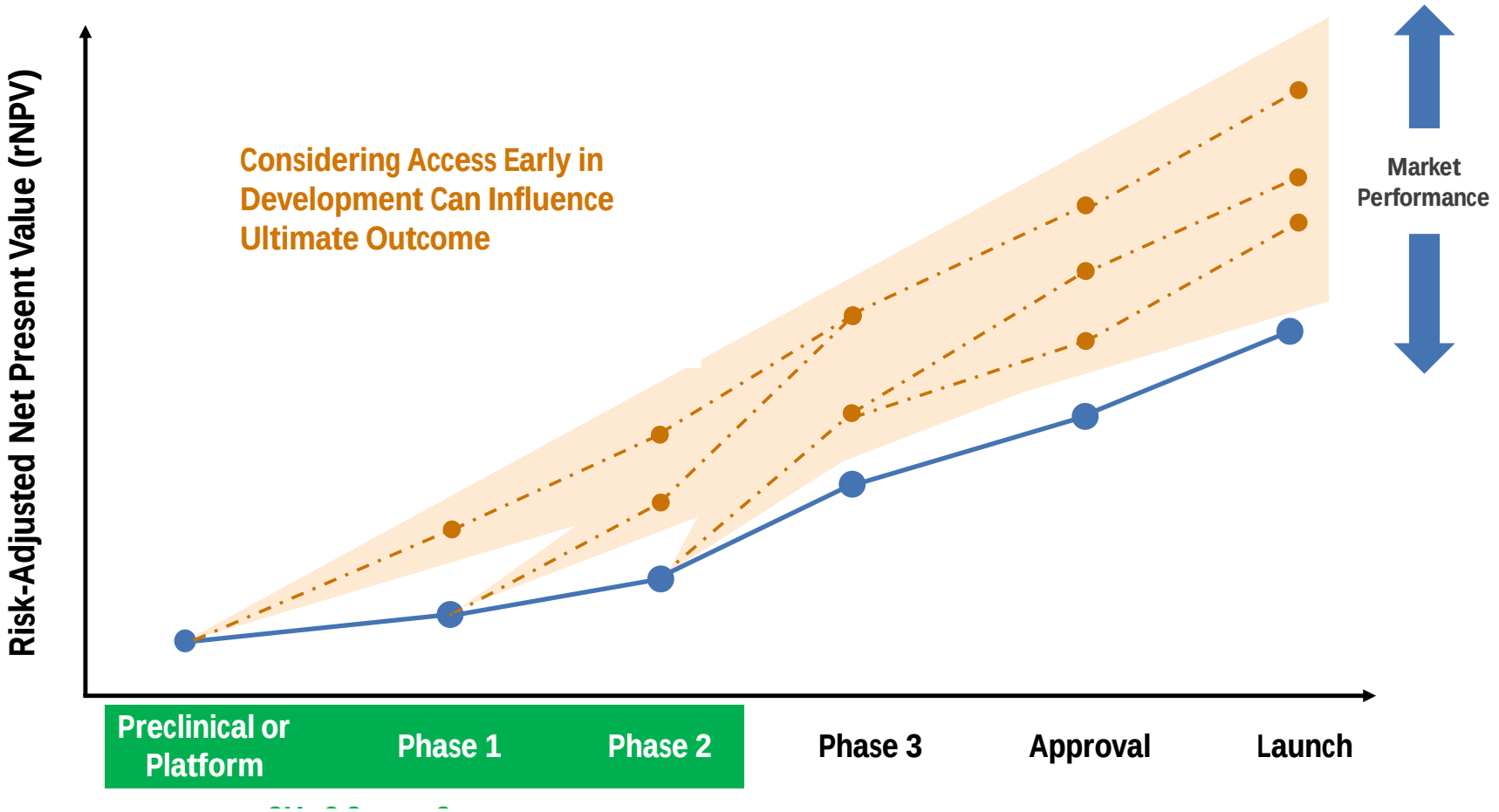
Strategic Focus on Value Creation for Early-Stage Biotech



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Webinar Panelists

ROGER LONGMAN

CHAIRMAN

REAL ENDPOINTS

Mr. Longman has been involved with the health care industry for over 30 years and is recognized as an expert in biopharmaceutical strategy and reimbursement. Mr. Longman often speaks at key industry events organized by important trade organizations, investment banks, venture capital firms, and leading biopharma companies. His most recent focus has been on new value-based approaches to paying for drugs and diagnostics, harnessing tools and systems for objective, transparent analysis of drug value and economic impact. He is developing these initiatives in collaboration with major provider, payer, pharmaceutical and diagnostic companies, and patient organizations.

At his first venture, Windhover Information, he and his team created several industry-standard analytical sources, including IN VIVO and Start-Up, the strategic transactions database and a conference business.

JEFFREY BERKOWITZ

CEO AND DIRECTOR

REAL ENDPOINTS

Mr. Berkowitz is one of the rare top executives whose career has spanned most key verticals in global healthcare — with executive committee and other senior roles at United Health Group, Walgreens Boots Alliance (formerly Walgreens), Merck and Schering-Plough.

He joined RE from UnitedHealth Group/Optum where he led Optum's International division as CEO while also driving key strategic initiatives within Optum's pharmacy benefits management division. Previously, Mr. Berkowitz served as President of Pharma and Global Market Access at the Walgreens Boots Alliance. He joined Walgreens from Merck & Co., where, as SVP of global market access. Mr. Berkowitz had held a similar position at Schering-Plough, where he started as legal director for Schering-Plough's managed care and commercial group in 1998.

DENNIS PURCELL

FOUNDER AND SENIOR ADVISOR

AISLING CAPITAL LLC

Dennis is founder and senior advisor at Aisling Capital. During his tenure, Dennis has been directly involved with over two hundred completed transactions and supervised over $15 billion of financing and advisory assignments in the pharmaceutical, biotechnology and medical products industries. Dennis is a frequent commentator on the industry and has been honored in various publications as a top contributor to the Life Sciences industry. He sits on numerous private and public healthcare company boards. He is actively involved with many of the industry's professional organizations.

Mr. Purcell is a member of The University of Delaware Investment Committee, Harvard Kennedy School - M-R CBG Advisory Council, and the New York Leadership Council.

He received his M.B.A. from Harvard University and his B.S. in Accounting from the University of Delaware.

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