The Dash to Treat NASH, Looking Beyond the Finish Line

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Defined Health Insight Series Webinar
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May 8 – 9, 2018
New York, NY
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- **BioPharm America** | September 26 - 27, 2017 | Boston, MA | [https://ebdgroup.knect365.com/biopharm-america/](https://ebdgroup.knect365.com/biopharm-america/)
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- **BioEurope** | November 6 - 8, 2017 | Berlin, Germany | [https://ebdgroup.knect365.com/bioeurope/](https://ebdgroup.knect365.com/bioeurope/)
- **ASH Annual Meeting** | December 9 - 12, 2017, Atlanta, GA | [http://www.hematology.org/Annual-Meeting/](http://www.hematology.org/Annual-Meeting/)
Defined Health has Been Following Developments in Fibrosis and NASH Since 2012 and has Conducted Numerous Evaluations in these Spaces

♦ DH Insight Briefing, May, 2012 – Novel Therapeutics for Fibrotic Disease: Has Their Time Finally Arrived?
  • David J. Lomb, PhD, Associate Principal, Defined Health

♦ DH Insight Briefing, March, 2015 – The Dash to Treat NASH, the Next Big Global Epidemic
  • David J. Lomb, PhD, Associate Principal, Defined Health
  • Brent A. Tetri, M.D., Director of the Division of Gastroenterology & Hematology, Saint Louis University School of Medicine

♦ BIO Europe Spring, April, 2016 – After Inflammation, Fibrosis: Will Biopharma Follow Nature's Lead?
  • David J. Lomb, PhD, Associate Principal, Defined Health
  • Donnie McGrath, MD, MPH – VP, Search and Evaluation, BMS
  • Elias Papatheodorou – CEO, Genkyotex
  • Hans T. Schambye, MD, PhD – CEO, Galecto Biotech
  • Matthias Corbascio, MD, PhD – VP, IsletOne Therapeutics

♦ NASH Summit Workshop, April, 2017 – The Dash to Treat NASH: the Race is Heating Up!
  • David J. Lomb, PhD, Associate Principal, Defined Health
  • Brent W. Osborne, PhD, Consultant, Defined Health, a Cello Health business
  • Manal F. Abdelmalek, MD MPH, Associate Professor, Gastroenterology and Hepatology, Director NAFLD Clinical Research Program, Duke University
Non-Alcoholic Fatty Liver Disease (NAFLD) Encompasses a Spectrum of Disease Ranging from Simple Steatosis (NAFL) to Steatohepatitis (NASH) and Cirrhosis

- Non-alcoholic fatty liver (NAFL) describes a clinical entity in which patients have an accumulation of lipids in the liver (i.e., hepatic steatosis), but no inflammation or fibrosis.
- Non-alcoholic steatohepatitis (NASH) describes a distinct clinical entity in which patients lack a history of significant alcohol consumption but have liver biopsy findings indistinguishable from alcoholic steatohepatitis (i.e., hepatic steatosis, lobular inflammation, and hepatocellular ballooning).
- It is estimated that 25-40% of patients with NASH will develop progressive liver fibrosis and 20-30% of these individuals will develop liver cirrhosis.
- Fibrosis stage, but no other histologic feature of NASH, is independently associated with long-term overall mortality, liver transplantation, and liver-related events.

The Spectrum of NAFLD

Insulin Resistance Plays a Key Role in the Pathogenesis of NASH, Leading to Hepatic Steatosis and Sensitizing to Subsequent Metabolic Insults

- Factors leading from hepatic fat accumulation to the inflammatory changes and cell injury characteristic of NASH have not yet been fully elucidated.
- Most experts believe that a “two-hit” or “multiple-hit” model best explains this process.
- The initial hit is development of insulin resistance leading to an increased uptake and synthesis of free fatty acids resulting in hepatic steatosis.
- Cytokines, adipokines, bacterial endotoxins, mitochondrial dysfunction, endoplasmic reticulum stress, and especially oxidative stress have all been hypothesized to act as the “second hits” responsible for progression from simple steatosis to NASH.

NASH is Expected to Become the Most Common Cause of Advanced Liver Disease in the Coming Decades

- The prevalence of NAFLD is highest in populations with pre-existing metabolic conditions such as obesity and type II diabetes, and given the growing epidemic of obesity and diabetes, the prevalence and impact of NAFLD is expected to increase.
- Most U.S. studies estimate the prevalence of NAFLD at 10-35% (~70M) and it is estimated that 10-30% of these patients have NASH (~16M).
- Liver biopsy is required to make a definitive diagnosis of NASH and estimates from biopsy series estimate prevalence of NASH in the U.S. at 3-5% overall (~13M) and at ~37% in the morbidly obese.

NASH is Also Expected to Become the Leading Indication for Liver Transplant in the Next 10-20 Years

♦ According to data from the Scientific Registry of Transplant Recipients from 2001-2009, NASH was the third leading indication for liver transplant in the US, and will be the leading indication in the next 10-20 years.

♦ According to United Network for Organ Sharing (UNOS) and Organ Procurement and Transplantation Network (OPTN) registry data from 2004-2013, NASH is now the second-leading disease among liver transplant waitlist registrants, after HCV.

♦ However, cardiovascular disease remains by far the most common cause of death in patients with NASH.
Liver biopsy is Required to Diagnosis NASH, but Clinicians are Most Concerned About Liver Fibrosis which Can be Assessed Non-Invasively

- NAFLD is typically first identified by a PCP on routine exam based on persistent abnormalities in liver function tests coupled with metabolic risk factors (e.g., obesity, diabetes, metabolic syndrome).

- Such patients are typically referred to a hepatologist who will first confirm NAFLD by ultrasound (US) and then rule out alternative causes of fatty liver (e.g., HCV/HBV, alcohol).

- **Once NAFLD is confirmed, most hepatologists risk stratify based on clinical parameters (e.g., diabetes, platelet count, etc.) and/or a non-invasive measure of fibrosis (e.g., Fibroscan) as the presence of fibrosis is the best predictor of poor outcome.**

- Liver biopsy is typically reserved for patients at high risk of advanced fibrosis whose Fibroscan reading was inconclusive and those enrolling in clinical trials.

DH Primary Research; Frontline Gastroenterol. 2014 Jul;5(3):211-218
There are No Drugs FDA-Approved Specifically for the Treatment of NAFLD or NASH and No Universally Accepted Pharmacological SoC

- Lifestyle modification aimed at weight loss and increased physical activity as well as treatment of any associated metabolic risk factors is the recommended treatment for most patients.
- Patients with significant fibrosis are at highest risk of developing progressive liver disease and pharmacotherapy with pioglitazone or vitamin E may be considered.
- For patients who have progressed to cirrhosis, surveillance for HCC is essential.

With an estimated 16-30 million adults affected in the U.S. alone and no FDA approved treatments, non-alcoholic steatohepatitis (NASH) has been proclaimed “the Next Big Global Epidemic” and “the Next Hepatitis C.” Indeed, analysts now forecast that the market for NASH treatments could reach $35-40 Billion by 2025.

Treatment Options:
- Diet and exercise
- Pioglitazone
- Vitamin E

Treatment Options:
- Diet and exercise
- Pioglitazone
- Pentoxifylline
- Endoscopy to screen varices
- Screening for HCC

There are More than 200 Assets in Development for NASH and Experts are Confident that at Least One will be Approved in the Next Few Years

♦ NASH is a very active area of drug development and it appears very likely that one or more drugs will be approved for this indication within the next few years.

♦ Targets of most interest include FXR agonists and repurposed anti-diabetic agents, as well as anti-steatotic & anti-inflammatory approaches.

♦ The most advanced programs are Intercept’s obeticholic acid (FXR agonist) and Genfit’s Elafibranor (PPARα/δ agonist), both of which are well into Phase III.

- Of the 252 agents in the pipeline, 205 of those are being developed in the US, EU, JP, Australia, or Israel (1/6 P3 agents and 46/246 PreClin-P2 agents being developed in Iran, China, India, S. Korea, Taiwan, or Hong Kong).
The Pipeline Includes Multiple Therapeutic Approaches Covering Key Early, Intermediate, and Late Events in the Pathogenesis of NAFLD/NASH

**ACC inhibitor**  
GS-0976: Gilead  
Bile acid conjugate  
Aramchol: Galmed

**Caspase inhibitor** Emricasan: Conatus  
**SSAO inhibitor** PSX4728A: Pharmaxis/BI

**Galectin-3 inhibitor** GR-MD-02: Galectin Therapeutics

**MAP3 kinase/ASK1 inhibitor** GS4997: Gilead

**FXR agonist** Obeticholic acid: Intercept; GS 9674: Gilead/Phenex  
**PPAR agonists** GFT505: Genfit  
**FGF-21 analogues** BMS-986036, BFKB8488A: Genentech

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Adis R&D Insight; Thompson Reuters Cortellis; clinicaltrials.gov; DH Analysis

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However, Most Agents Being Developed for NAFLD are Targeting a Population of NASH Patients with at Least Some Degree of Fibrosis (≥F1)

<table>
<thead>
<tr>
<th>Drug</th>
<th>MOA</th>
<th>NAFL</th>
<th>F0</th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
<th>≥F4</th>
</tr>
</thead>
<tbody>
<tr>
<td>OCA ( Intercept )</td>
<td>FXR agonist</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Elafibranor (Genfit)</td>
<td>PPARα/δ agonist</td>
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<td></td>
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<tr>
<td>Emricasan (Conatus/Novartis)</td>
<td>Caspase inhibitor</td>
<td></td>
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<tr>
<td>Cenicriviroc (Allergan)</td>
<td>CCR2/CCR5 antagonist</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Aramchol (Galmed)</td>
<td>Bile acid conjugate</td>
<td></td>
<td></td>
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<tr>
<td>Selonsertib (Gilead)</td>
<td>MAP3K5/ASK1 inhibitor</td>
<td></td>
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<tr>
<td>GR-MD-04 (Galectin Therapeutics)</td>
<td>Galectin 3 inhibitor</td>
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</tbody>
</table>

- **OCA (Intercept)**
  - FXR agonist
  - **F1** pts are exploratory cohort with concomitant diabetes, obesity or elevated ALT

- **Elafibranor (Genfit)**
  - PPARα/δ agonist
  - **F1** trial enrolling NAS≥4 + F1-F3
  - F1 subjects + cardiometabolic comorbidities associated with rapid NAFLD progression

- **Emricasan (Conatus/Novartis)**
  - Caspase inhibitor
  - Phase 2b ENCORE-NF enrolling NAS≥4 + F1-F3
  - F1 subjects limited to 20% cohort and must have diabetes/metabolic syndrome

- **Cenicriviroc (Allergan)**
  - CCR2/CCR5 antagonist
  - P3 AURORA enrolling biopsy-proven F2/F3

- **Aramchol (Galmed)**
  - Bile acid conjugate
  - P2a study enrolled cohort with histologically confirmed NAFLD (F0-F2) or NASH based on a biopsy (F3)

- **Selonsertib (Gilead)**
  - MAP3K5/ASK1 inhibitor
  - P3 STELLAR 3: Liver biopsy consistent with NASH and bridging fibrosis
  - P3 STELLAR 4: Liver biopsy consistent with NASH and cirrhosis

- **GR-MD-04 (Galectin Therapeutics)**
  - Galectin 3 inhibitor
  - P2a NASH-FX trial enrolled advanced NASH patients
  - P2 NASH-CX trial enrolling Ishak 5/6 cirrhosis due to NASH

Adis R&D Insight; Thompson Reuters Cortellis; clinicaltrials.gov; DH Analysis

NASH Insight Briefing
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## NASH has Become an Active Space for Partnering and Value Inflection is High For Programs Targeting Each Segment of Disease

<table>
<thead>
<tr>
<th>Company</th>
<th>Asset</th>
<th>MOA</th>
<th>Status at Time of Deal</th>
<th>Value Inflection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Conatus Pharmaceuticals</strong></td>
<td>Emricasan</td>
<td>Oral pan-caspases inhibitor</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; in class, mid-Ph2</td>
<td>Novartis signs exclusive license for $50M up-front plus milestones: Conatus stock value rises 250% December, 2016</td>
</tr>
<tr>
<td><strong>Nitto Denko</strong></td>
<td>ND-L02-s0201</td>
<td>HSP47 siRNA, reported to regulate collagen synthesis/secretion and penable resolution of fibrosis</td>
<td>Open-label Ph1b in patients with F3-F4 fibrosis due to NASH or HepC - Fast-Track Designation</td>
<td>BMS acquires exclusive WW rights for $100M + milestones November, 2016</td>
</tr>
<tr>
<td><strong>Tobira</strong></td>
<td>Cenicriviroc (CVC) and Evogliptin</td>
<td>CVC: oral CCR5/CCR2 antagonist Evo: oral DPP-4 antagonist</td>
<td>Ph2b complete, but failed primary endpoint of NAS, however fibrosis improvement was observed</td>
<td>Allergan buys Tobira for $595 up-front (498% share premium) and potential $1.1B in milestones September, 2016</td>
</tr>
<tr>
<td><strong>Nimbus Therapeutics</strong></td>
<td>Portfolio of acetyl-coenzyme A carboxylase inhibitors</td>
<td>Hepatoselective fatty acid synthesis and degradation</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; in class, Ph2 ready, addresses muscle tox concerns</td>
<td>Gilead acquired ACC portfolio for $1.2B April 2016</td>
</tr>
<tr>
<td><strong>Pharmaxis</strong></td>
<td>Semicarbazide-Sensitive Amine Oxidase/Vascular Adhesion Protein-1 (SSAO/VAP-1) Inhibitor PXS4728A</td>
<td>Decreases inflammation by blocking leukocyte adhesion and tissue infiltration</td>
<td>Ph1 Oral therapy targeting same MOA as Gilead’s mAb</td>
<td>Boehringer pays $31M up front and $222M in milestones May, 2015</td>
</tr>
<tr>
<td><strong>Phenex</strong></td>
<td>Entire Farnesoid X Receptor (FXR) program</td>
<td>FXR agonist</td>
<td>Mid-Phase 2 with lead asset Px-104, in NASH</td>
<td>Gilead acquires FXR portfolio for $470M January, 2015</td>
</tr>
</tbody>
</table>
Population Based Estimates Suggest a Very Large Number of Individuals with NASH, but the Addressable Patient Population May be Much Smaller

- Population based studies estimate prevalence of NAFLD in the U.S. at 10-35% (~70M).
- However, patients at risk of NAFLD are typically identified by routine blood tests showing elevations in liver enzymes (i.e., ALT, AST, GGT).
- Importantly, liver enzymes are not elevated in all NAFLD patients and many individuals do not undergo routine wellness exams, thus many patients with NAFLD are not currently being diagnosed.
- It is estimated that 10-30% of patients with NAFLD have NASH (~16M), and 25-40% of these patients will develop progressive liver fibrosis.
- However, only a small percentage of patients currently undergo liver biopsy and non-invasive methods are not very good at identifying patients with early fibrosis.
- Accordingly, the number of NASH patients who are currently being diagnosed may be much smaller than population based estimates would suggest.

*The current low diagnosis rate is at least partly due to the lack of effective treatment options and it seems likely that diagnosis rates will increase once an effective treatment is approved.*

Payers May Restrict Access to NASH Drugs, Especially if they Are Priced Such that they Do Not Meet Current Willingness to Pay Thresholds

- Intercept launched Ocaliva (OCA) for PBC at a WAC of $5,700 for 30 tablets (5 or 10 mg) which equates to $68,400/year/person based on once/daily dosing.
- Most analysts predict that Intercept will lower the price of OCA considerably should it be approved for NASH to somewhere between $12,500-$33,000/person/year.
- However, a draft evidence report recently published by the US-based Institute for Clinical and Economic Review (ICER) calculated that **even at a price of $15,000, OCA would not meet current willingness to pay thresholds ($100,000/QALY in the U.S.).**
- Accordingly, unless a NASH drug were priced much lower or provided much greater benefit, payers may restrict access significantly.

<table>
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<th>Cost-Effectiveness of OCA When the Annual Cost of OCA is $65,000/Year</th>
<th>Placebo</th>
<th>OCA</th>
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<tr>
<td>Undiscounted Life Years</td>
<td>16.45</td>
<td>17.36</td>
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<tr>
<td>Discounted QALYs</td>
<td>10.91</td>
<td>11.02</td>
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<tr>
<td>Discounted Total Cost</td>
<td>$70,300</td>
<td>$351,000</td>
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<tr>
<td>ICER ($/QALY)</td>
<td>$2,574,200</td>
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<td>Discounted Total Cost</td>
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<td>$131,000</td>
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<tr>
<td>ICER ($/QALY)</td>
<td>$549,900</td>
<td></td>
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</table>

Institute for Clinical and Economic Review (ICER), Draft Evidence Report, May 25, 2016; Redbook
Questions for Discussion:

♦ What will a label indication for NASH look like?

♦ How will clinicians determine which NASH patients to treat?

♦ How will clinicians identify these patients in clinical practice?

♦ What criteria will payers use to determine eligibility for reimbursement?

♦ How will the pricing of drugs for NASH influence market access and reimbursement?

♦ Once multiple drugs are approved, how will payers manage access to combination therapy?

♦ What can companies developing drugs for NASH do to maximize their share of the market and to facilitate access/reimbursement?
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♦ How will the pricing of drugs for NASH influence market access and reimbursement?

♦ Once multiple drugs are approved, how will payers manage access to combination therapy?

♦ What can companies developing drugs for NASH do now to help realize the full potential of this market?
Manal F. Abdelmalek, MD MPH
Associate Professor, Gastroenterology and Hepatology, Director of NAFLD Clinical Research Program, Duke University

- Manal F. Abdelmalek, MD, MPH is an Associate Professor of Medicine in the Division of Gastroenterology and Hepatology at Duke University and Director of the NAFLD Clinical Research Program at Duke University.
- She received a combined BA/MD degree from the University of Missouri-Kansas City and subsequent training in Internal Medicine, Gastroenterology and Hepatology at the Mayo Clinic, Scottsdale AZ and Rochester, MN.
- She obtained a MPH degree with emphasis in epidemiology, public health and clinical investigation at the University of Florida, Gainesville, Florida.
- Her clinical and research area of interest is in the field of nonalcoholic fatty liver disease (NAFLD) since reporting the first case of NASH progressing to cirrhosis over 20 years ago. She has expertise in the design and conduct of clinical trials of investigator-initiated, industry sponsored and NIH-funded clinical trials evaluating new therapies and biomarkers for NAFLD as well as the translation of clinic-to-bench and bench-to-clinic research to define pathogenic mechanisms underlying NAFLD acquisition and progression.
- Dr. Abdelmalek is a Fellow of American College of Physicians, American College of Gastroenterology and American Association for the Study of Liver Disease. She is a standing member of NASH Clinical Research Network (NASH CRN) and NIH NIDDK Study Section for Training and Mentored Career Awards. She has over 130 publications authored publication in the field of liver disease and mostly within the area of NAFLD.
Roger Longman, Chief Executive Officer, Real Endpoints

♦ Roger Longman is CEO of Real Endpoints, a start-up company focused on pharmaceutical reimbursement, and aiming to help both payers and product developers improve the value of pharmacotherapy. Its first product assesses – systematically, objectively, and transparently – the value of drugs relative to their competitors.

♦ Until November 2009, Longman was Managing Director, Pharma at Elsevier Business Intelligence, a Reed Elsevier company. He has been involved with the health-care industry for more than 25 years.

♦ From 1990 through 2008, Longman was co-CEO and managing director of Windhover Information, a company providing analysis and data around pharmaceutical and medical device business strategy through publications, databases and conferences. Longman co-founded and built the company through internal development (with publications such as IN VIVO, Start-Up and The RPM Report, several databases, including The Strategic Transactions Database; and a series of senior-executive conferences), and through acquisition.

♦ In 2008, Windhover was acquired by Reed Elsevier and merged with its FDC Reports division (publishers of The Pink Sheet, The Gray Sheet and many other medical-industry newsletters), creating Elsevier Business Intelligence. Longman ran the combined group’s pharmaceutical business until he left in 2010 to begin working on Real Endpoints with Norman Selby, who had been Windhover’s chairman and lead investor.

♦ Over the years, Mr. Longman has become recognized as an expert in biopharmaceutical strategy and often speaks at key industry events organized by important trade organizations, investment banks, venture capital firms and leading pharma and biotech companies. He lectures regularly at several leading universities and co-directed the Wharton-Windhover pharmaceutical program at The Wharton School. Mr. Longman completed his BA at Cornell University and an MA at the University of North Carolina at Chapel Hill, and then taught for three years at the European division of the University of Maryland.
David J. Lomb, PhD

Associate Principal, Defined Health, a Cello Health business

♦ As an Associate Principal with Defined Health, David participates in and leads opportunity assessments as well as indication prioritization/sequencing, search, and strategy projects. David regularly contributes to projects in the oncology, dermatology, CNS, and autoimmune and inflammatory disease spaces. In addition, David leads the fibrosis therapeutic area practice at Defined Health.

♦ Prior to joining Defined Health in 2010, David was a postdoctoral fellow in the Paul F. Glenn Laboratories for the Biological Mechanisms of Aging at Harvard Medical School. As a scientist at Harvard, David studied a family of enzymes known as sirtuins which have been implicated in the regulation of aging and age-related diseases. Also while at Harvard, David was a fellow in the Early Technology Assessment Program sponsored by the Office of Technology Development. In this position, David was responsible for performing initial commercial assessments of discoveries made by Harvard faculty members.

♦ David earned a PhD in Pharmacology from the University of Rochester, in Rochester, New York, where his thesis work focused on the molecular mechanisms of neuronal programmed cell death. David has also earned Bachelor of Science degrees in both Biochemical Pharmacology and Psychology from the University at Buffalo, in Buffalo, New York. David has published in peer reviewed scientific journals and has presented his work at national scientific meetings.

♦ David has conducted market research studies involving numerous indications characterized by or associated with fibrosis including idiopathic pulmonary fibrosis (IPF), primary sclerosing cholangitis (PSC), primary biliary cirrhosis, non-alcoholic steatohepatitis (NASH), and systemic sclerosis. In addition, David has presented webinars covering key issues regarding drug development for fibrosis in general and NASH in particular.
As a Consultant with Defined Health, Brent participates in opportunity assessments, indication prioritization, and strategy projects and regularly contributes to projects across therapeutic areas.

Before joining Defined Health, Brent was a postdoctoral fellow in the Wu Center for Molecular Cardiology at Columbia University, where he studied the molecular mechanisms of smooth muscle function, leading to the development of two novel mouse models of hypertension. In parallel to his time at Columbia, Brent worked as an analyst for The Solution Lab (TSL), a non-profit life sciences consulting firm in NYC, where Brent advised clients in both pharma and biotech firms develop business strategies through competitive intelligence and quantitative analyses of niche markets.

Brent earned a PhD in Cell and Molecular Biology from the University of Vermont, in Burlington, VT, where his thesis focused on structure-function relationships of novel modulators of protein kinase activity. Brent also earned a BSc from UVM in Biological Sciences where he studied the mechanisms of microbial pathogenesis. Brent has published in peer-reviewed journals, presented his work at national and international scientific meetings and is co-inventor on a patent originating from his graduate studies.
Defined Health is pleased to present:

BioEurope Spring 2018
March 12 – 14, 2018
Amsterdam, The Netherlands
www.therapeuticinsight.com

29TH Annual Cancer Progress Conference
May 8 – 9, 2018
New York, NY
www.cancerprogressbyDH.com

Defined Health will also be participating in the following industry events:

- Discovery on Target, NASH & Fibrosis | September 26 - 27, 2017 | Boston, MA | http://www.discoveryontarget.com/NASH-Fibrosis/
- LES Annual Meeting | October 22-25, 2017 | Chicago, IL | http://www.lesusacanada.org/mpage/am17
- BioEurope | November 6 - 8, 2017 | Berlin, Germany | https://ebdgroup.knect365.com/bioeurope/
- ASH Annual Meeting | December 9 - 12, 2017, Atlanta, GA | http://www.hematology.org/Annual-Meeting/