



North America
United States
Health Care
Biotechnology

Industry
**Nonalcoholic
Steatohepatitis
(NASH)**

Date
14 July 2014

Industry Update

NASH- the next big global epidemic in 10 years?

Your guide to NASH and the future landscape

Along with our launch on Intercept & Genfit, we conducted a robust analysis on NASH after industry, doc, co, and literature checks. In this 59 pg report, we address 1) causes, 2) emerging therapies, 3) expectations for key trials, and 4) potential market size for NASH. In summary, we think NASH is a real disease growing in prevalence globally which leads to a big mkt oppy.

We think both Intercept & Genfit's therapies will clear NASH, but may be too early for a stat sig trend on fibrosis

We are focused on NASH clearance for both therapies. We note less effective therapies have met this endpoint before. We think that the duration in both studies (52-72 wks) may be too short to be stat sig on fibrosis. We believe fibrosis is reversible w/ both therapies since clearing chronic liver injury should help fix the fibrosis & these drugs have their own anti-fibrotic properties too.

We expect more FDA guidance around the NASH regulatory pathway before 2014 ends. Here is what we think is the likely outcome

We think that surrogate endpoints will be acceptable and that likely surrogates are NASH clearance for pre-cirrhotics and the hepatic venous pressure gradient (HVPG) for cirrhotics. Along with the surrogate endpoints, we expect outcome studies will be needed and as a result the first NASH therapies get to market ~2019.

We believe these oral therapies will be used at least in advanced NASH patients (F3/F4) and we expect that population to grow after looking at trends

We expect that the factors which drive NASH (like diabetes and central obesity) will continue to increase in prevalence globally. We think to treat NASH is to treat the underlying metabolic dysfunction. We estimated around 6.5M adults in BOTH the US & Big5 EU have advanced NASH today.

We think ultimately there will be many drugs on market for NASH, but Intercept, Genfit, and Gilead are in the lead and could be dominant

We think that the NASH treatment paradigm may ultimately involve combinations in certain populations. We believe NASH clearance is necessary first. Intercept, Genfit, and Gilead (interim at 48 wks) all have important data reading out in the next 12 mos. Simtuzumab (GILD) is an exciting anti-fibrotic that's organ agnostic and could be a more potent agent for reversing fibrosis.

We estimate a peak NASH market opp'y of \$35-40B by 2025. We have built an integrated NASH model that drives our estimates for all companies

We current think about 300K US & EU5 pts have been diagnosed with NASH. We think by 2025 that ~10x patients will be diagnosed driven by new treatments & non-invasive diagnostic methods. We estimate that about 1M pts will be treated with different NASH therapies by 2025. In 2010, there was roughly \$600M in off-label sales for NASH therapies, and we estimate dramatic growth. For Intercept, Genfit, and Gilead each, we estimate potential peak sales of \$10-\$12B/yr.

A big global oppy for ICPT, GNFT-FR, and GILD is ahead. Valuation and Risks

We see upside to valuations of Intercept, Genfit, and Gilead based on potential market oppy in NASH. We use a probability adjusted DCF analysis. We are hosting a NASH deep dive call this **Fri 7/18 at 10am ET. Dial in: 1-800-309-8606/ID: 74141380**. Risks include small NASH mkt & clinical failure & delays.

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Key Changes

Company	Target Price	Rating
ICPT.OO	- to 395.00(USD)	NR to Buy
GNFT.PA	- to 110.00(EUR)	NR to Buy

Source: Deutsche Bank

Companies Featured

Intercept (ICPT.OO),USD222.20	Buy		
	2013A	2014E	2015E
EPS (USD)	-3.16	-2.17	-5.89
P/E (x)	-	-	-
EV/EBITDA (x)	-	-	-
Genfit (GNFT.PA),EUR23.91	Buy		
	2013A	2014E	2015E
EPS (EUR)	-	-	-
P/E (x)	-	-	-
EV/EBITDA (x)	-	-	-
Gilead Sciences (GILD.OO),USD88.73	Buy		
	2013A	2014E	2015E
EPS (USD)	2.16	6.65	9.76
P/E (x)	25.9	13.3	9.1
EV/EBITDA (x)	16.6	9.0	6.3

Source: Deutsche Bank

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