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Achillion Pharmaceuticals

Pharma & biotech

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Moving towards an all-oral combination

Achillion holds the promise of developing an all-oral HCV regimen that can be competitive in the evolving HCV treatment landscape. It is the only small-cap biotech company with HCV drug candidates in three key classes – NS5A, nucleotide NS5B polymerase and protease inhibitors. Early pre- and clinical data for these candidates demonstrated strong potency and favourable drug profiles. Further Phase II clinical trials would provide efficacy data for various combinations, potentially leading to partnerships. Achillion is funded until 2016, after critical Phase II combination data become available: positive data should be a major value inflection point.

Creating a competitive combination HCV regimen

Gilead, the leader in HCV therapy, has developed an oral, ribavirin (RBV)-free NS5B + NS5A inhibitor regimen (sofosbuvir + ledipasvir) that achieved >90% cure rate in genotype 1 treatment-naïve patients with only eight weeks of treatment. Achillion's NS5A inhibitor, ACH-3102, and NS5B inhibitor, ACH-3422, have shown equal or better potency in preclinical and clinical studies so far. Adding ACH-2684, a potent protease inhibitor (PI), Achillion has what it takes to create a HCV regimen that matches Gilead's and could potentially shorten treatment duration to six weeks.

Key triple combination efficacy data in 2015

A Phase II all-oral combination trial of ACH-3422 (NS5B) and ACH-3102 (NS5A) ± ACH-2684 (PI) could start in early 2015, potentially generating efficacy (cure rate) data later in the year. If the data match that of Gilead's sofosbuvir (NS5B) + ledipasvir (NS5A) combination, Achillion (or together with a partner) could advance its regimens into Phase III in early 2016, leading to potential approval and launch in 2017/18. Key Phase II efficacy data would be a major value driver given the high correlation between Phase II and III results for HCV drugs.

Valuation: EV of $176m

Achillion's modest EV of c $176m, relative to another HCV company, Idenix (EV of c $743m with three HCV drugs of two classes in Phase I and II trials), reflects the market's concern about sovaprevir's clinical hold and its possible implication on ACH-2684. Achillion is preparing a complete response package addressing its PI, sovaprevir, which was placed on clinical hold in July 2013 due to liver enzyme elevation in a Phase I drug-drug interaction study. An FDA decision, potentially by end-H114, on the lift of the clinical hold would be a major near-term stock catalyst and would enable sovaprevir development to resume.

Consensus estimates

Year end	Revenue ($m)	PBT ($m)	EPS ($)	DPS ($)	P/E (x)	Yield (%)
12/12	2.6	(47.1)	(0.64)	0.0	N/A	N/A
12/13	0.0	(58.9)	(0.63)	0.0	N/A	N/A
12/14e	0.0	(75.2)	(0.77)	0.0	N/A	N/A
12/15e	47.0	(83.3)	(0.90)	0.0	N/A	N/A

Source: Bloomberg

Price	$3.08
Market cap	$298m

Share price graph

Share details

Code	ACHN
Listing	NASDAQ
Shares in issue	96.8m

Business description

Achillion is a US biotech company focused on infectious disease, particularly chronic hepatitis C (HCV). ACH-3102, an NS5A inhibitor, is in a Phase II HCV trial. Other HCV drug candidates include ACH-2684, a protease inhibitor (PI) in Phase I and ACH-3422, a nucleotide NS5B polymerase inhibitor, in pre-IND testing. Another PI, sovaprevir, which is in an ongoing Phase II trial (study 007), is currently on clinical hold meaning no new trials can be initiated.

Bull

- Ribavirin (RBV)-free anti-HCV regimen has blockbuster potential.
- Could attract a strategic partner or buyer.
- $158m of cash and cash equivalents at end of 2013, sufficient until 2016.

Bear

- Behind in the RBV-free anti-HCV regimen race.
- Sovaprevir on clinical hold since July 2013.
- Additional cash needed without partner.

Analysts

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