

Recent Events: XTLbio completed \$28M round from top U.S. biotech institutional investors; company initiated clinical study for a second clinical-stage compound in hepatitis C; changes in senior management tightens clinical focus and improves cost structure.

XTL Biopharmaceuticals Ltd. (XTLbio), headquartered in NYC, was founded in Israel in 1993 to develop drugs against infectious diseases, with a particular focus on HCV treatments. The company has set its sights on several development programs for HCV drug candidates to address the global HCV infection concern -- and the attractive market opportunity it presents.

In fact, XTLbio is the only biotechnology company with two compounds currently in clinical development for the treatment of hepatitis C.

HIGHLIGHTS

- XTLbio and only eight other biotechnology companies are known to be clinically developing new drugs to treat the hepatitis C virus (HCV), the leading cause of chronic liver disease that is the tenth major cause of death in the US.

- The hepatitis C disease area is unique in that even Phase I activity data is highly valued by Wall Street. This is because anti-viral activity of a compound can be detected very quickly, and therefore, Phase I studies can yield activity as well as safety information.

- Big pharma has shown a substantial appetite for doing deals in hepatitis C, even for pre-clinical and early clinical compounds. This is evidenced by robust deals such as Novartis-Anadys, Roche-Pharmasset, Novartis-Idenix, Gilead-Achillion, and Novartis-Genelabs—all of which have been signed in the last 18 months. This confirms a willingness to accept uncharacteristic risk in pursuing the \$10+ billion market that awaits the next generation of hepatitis C therapies.

- XTLbio's two lead HCV candidates are both in Phase I clinical trials, both of which are scheduled to be completed within 6-9 months.

- XTLbio began senior management changes in 2005. Michael Weiss, CEO of Keryx Biopharmaceuticals (NasdaqNM: KERX), was named chairman of the board in June. Under his leadership, Keryx's market value grew from roughly \$20 million to more than \$500 million in three years. To complete the transition,

XTL Biopharmaceuticals Ltd. (Nasdaq ADR: XTLB) (LSE: XTL.L)

Recent Price (ADRs):	\$3.55
Approx. Market Cap:	\$58 million
Combined Avg. Volume:	400,000
Fiscal Year Ends:	December 31

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Ron Bentsur, former VP, Finance of Keryx, was named XTLbio's CEO in January 2006.

CURRENT PIPELINE

XTL-6865 -- XTLbio is developing XTL-6865 under an FDA 'Fast Track' protocol. A dual-monoclonal antibody combination, XTL-6865 is comprised of the antibodies Ab68 and Ab65. XTL-6865 is targeted for two potential indications: preventing HCV recurrence following liver transplantation, and preventing relapse following treatment of patients with chronic HCV. The drug is in a Phase Ia multi-center clinical trial that has been designed to establish the safety and antiviral activity of the dual antibody in patients with chronic HCV. Results from this trial are expected by Q4 2006.

XTL-2125 -- XTL-2125 is an orally administered small molecule development program for the treatment of chronic hepatitis C. XTL-2125 targets the HCV polymerase -- a validated HCV viral target. The drug is currently in a Phase I multi-center clinical trial that has been designed to establish the safety and antiviral activity of the compound in patients with chronic HCV. Results from the study are expected in Q1 2007.

ACQUISITION DEEPENS HCV PROGRAMS

In August 2005, XTLbio announced the acquisition of closely held VivoQuest, Inc., specialists in a breakthrough small molecule chemistry technology known as Diversity Oriented Synthesis (DOS). The DOS technology, originally developed at the Harvard Institute of Chemistry and Cell Biology's Chemistry Laboratory, is also being used by Infinity Pharmaceuticals for oncology prod-

ucts. XTLBio plans to develop several small-molecule anti-HCV compounds based on the DOS technology.

As a result of the acquisition, VivoQuest advisors Drs. David Ho and Charles Rice have been named scientific advisors of XTLbio.

David Ho, MD is one of the world's foremost experts in the treatment of viral diseases. He is the founder of the Chemistry Laboratory at the Harvard Institute of Chemistry and Cell Biology where the DOS technology was originally developed. In 1996, Dr. Ho was named Time Magazine 'Man of the Year' for his antiviral research.

Charles Rice, PhD, a world-renowned leader in HCV research, is head of the Laboratory of Virology and Infectious Diseases at Rockefeller University.

ABOUT HEPATITIS

Hepatitis -- it's the liver disease that causes fatigue, jaundice and abdominal pain in most, and if untreated can lead to cirrhosis and liver failure in many. It is a virus that thrives and multiplies in the body's liver cells. Its two best-known strains, hepatitis A and hepatitis B, have historically been labeled as diseases of the underclass because of their primary modes of transmission.

The hepatitis A virus (HAV) is usually spread via food or water contaminated with fecal matter or through close contact with persons or objects that are contaminated. The hepatitis B virus (HBV) is most often passed between sexual partners and can also be spread by sharing needles or drug 'works.'

Luckily, vaccines for both HAV and HBV have been around since the 1990s and are widely available for at-risk populations (for HAV) and as part of routine childhood vaccinations (for HBV).

THIRD STRAIN EMERGES - HCV

But hepatitis has a third, lesser known, and more insidious strain that crosses all class barriers.

In the 1960s doctors starting seeing patients with liver disease whose blood

tested negative for both HAV and HBV. In 1988 the hepatitis C virus, or HCV, was identified as the third strain of the disease.

HCV is spread when infected blood enters the body and is introduced into the bloodstream. This can occur during procedures such as blood transfusions or organ transplants, and can also be caused by accidental needle sticks (common among healthcare workers) or sharing needles among intravenous drug users. It can also be passed from mother to baby via the umbilical cord during childbirth.

Who Gets HCV?

HCV infection occurs when blood from an infected person enters the body of a person who is not infected. The virus enters via the bloodstream and takes host and replicates within the liver.

- The majority of current HCV sufferers contracted the virus via blood transfusions prior to 1992; disease symptoms often go undetected for years
- Most newly transmitted cases of HCV are caused by needle-sharing among drug users
- HCV can also be transmitted via needle sticks or sharps exposure while on the job (medical workers), or possibly from tattooing
- Infection may occur via blood transfer from an infected mother to her child during childbirth

Today, stringent blood bank donor screening protocols and programs to prevent IV drug needles from being re-used have greatly reduced the number of new HCV infections caused by those methods of transmission. Despite these measures, however, HCV is the most common blood-borne infection in the US, with an estimated 3.9 million – or 1.8 percent - of Americans currently infected with the virus. And of that number, 2.7 million are chronically infected.

Here's the scary part: because the symptoms of HCV infection can be subtle and mild, more often than not the virus goes undetected in the body for a long period of time. In fact, only 30 percent of those infected with HCV have ever been diagnosed. Tests for the disease were not even available to doctors until the '90s. And although the disease tends to progress slowly, the outcome can be devastating.

According to the CDC, about 80 percent of those afflicted with HCV have no clear signs or symptoms of the disease other than some fatigue and mild depression – symptoms easily attributed to any variety of common ailments. Yet if left untreated, HCV is attributed to be the leading cause of liver disease requiring liver transplant in the US.

At this point there is no preventive vaccine for HCV available.

THE HCV RACE IS ON

More than 25 years have passed since interferon was first used to treat hepatitis C.

The current treatment of choice for HCV infection is a series of injections of a pegylated version of interferon, taken either alone or in combination with ribavirin. The treatment is expensive – a 12-month course can cost \$26,000. In addition, the common side effects are often so intolerable that many patients abandon the regimen before completion and many even refuse to go on interferon treatment at all.

Another drawback is that interferon/ribavirin treatment is ineffective in treating fewer than 50 percent of patients with HCV, and there is a high incidence of relapse even after treatment is completed.

Symptoms of HCV Infection

- Fatigue and mild depression in most.
- Chronic liver inflammation in some.
- HCV left untreated results in cirrhosis of the liver in upwards of 44 percent of infected individuals.
- Cirrhosis leads to liver failure in one out of five.

If the disease progresses to the point of liver failure, reinfection with HCV following liver transplantation almost always occurs since the transplanted liver immediately becomes vulnerable to the hepatitis C virus still present in the patient's bloodstream.

Currently, there's no treatment available to prevent this reinfection.

There is little wonder, then, that the prospect for developing a more effective, less invasive and better tolerated treatment for HCV has excited the pharma community – and piqued the interest of Wall Street. In recent months investors have seen a rapid increase in valuations of biotech companies whose HCV drug candidates showed early (Phase I) promise in reducing viral load.

Currently, nine companies are known to be developing treatments for HCV, including Anadys (ANDS), whose Phase I candidate was licensed to Novartis for upfront and milestone payments valued at \$570 million, and Idenix (IDIX), which licensed its HCV Phase IIb candidate to Novartis for upfronts, milestones and equity valued at \$630 million.

Eight other candidates are now in Phase I, including XTLbio's two compounds XTL-2125 and XTL-6865, for which data from both is expected within 6-9 months.

AND THE STAKES ARE HIGH

Each year, between 10,000 and 12,000 people in the US alone die from HCV. Globally, the World Health Organization estimates that about 190 million people are currently infected with HCV. In view of these staggering figures, analysts predict the current global market for HCV antiviral treatments, at approximately \$4.0 billion in 2005, has the potential to grow to over \$10 billion by 2015.

SUMMARY POINTS

- 1. XTLbio, with its two lead compounds for hepatitis C, is among the limited group of only nine companies with clinical-stage drugs for hepatitis C, a disease area in which patients and doctors are vying for new treatments. These companies are all trying to establish a leadership position in their respective classes in a market expected to grow from \$4 billion today to more than \$10 billion over the next 10 years.***
- 2. Several of the eight additional compounds (from companies including Anadys, Idenix, Achillion, and ViroPharma) have been out-licensed to big pharma at an unusually early stage – Phase I. The innovators of two others have not revealed plans to out-license. XTLbio's candidates, XTL-2125 and XTL-6865, remain available for licensing at a future date.***
- 3. XTLbio is sufficiently funded to complete all currently planned clinical programs.***
- 4. Management changes in 2005-06 streamlined operations, tightened clinical objectives and programs, and reset the company's growth path.***

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