Company: Cerus Corporation (CERS)
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Author: Eric Sharps, Ph.D.

We recently revisited a (short) investment thesis in Cerus Corporation (CERS). The stock continues to climb towards a $1 billion market capitalization (15.7 million shares at $52.27; $820 million) on hopes for regulatory approval of the company's first of several blood pathogen inactivation treatments. Cerus ended Q2 with $147 million of cash and is in its eighth year with committed partner, Baxter's Fenwal unit, which has invested over $150 million in the company. The short thesis has been predicated on the risk of a regulatory rejection and, if approved, poor market acceptance due to high cost and a modest risk/benefit profile.

Conclusion: *In the absence of foreseeable catalytic events, it is premature to short CERS at this time. Without question, the name should remain on an active watch list. With European approval likely before U.S. approval, market acceptance risk should be better clarified.*

Background: Cerus has developed a psoralen-based, photochemical pathogen inactivation system ("Intercept") to enhance the safety of blood products (platelets, plasma, red blood cells). Nucleic acid-containing organisms (including viruses) are rendered non-infectious by the procedure. The process is expected to add ≈ $70 to the cost of each unit.

A summary of the market for each of the three blood products follows, in order of Cerus's expected FDA filings:

Platelets: *≈3.5 million units/year WW*; 1.4 million N.Am + 1.3 million Europe + 700,000 Japan; Expect $75/unit inactivated on top of $250/pooled to $475/apheresis unit; Before 1981, platelets were stored for ≤ 3 days at room temperature (they irreversibly aggregate in the cold). FDA expanded this to five days in '81, then to 7 days in '84 and back to 5 days in late '86 (clock starts at time of withdrawal); 24 hours to process+test; bacterial contamination is #1 risk and (only) 4-6 people die each year due to bacterial contamination of platelet transfusions. 65 percent of platelets are from pooled collections, 35% from single-donor (aka apheresis) sources. Anticipated FDA approval in Q4/02; Europe in Q1/02.

Plasma: *≈8 million* 200-250mL *units/year WW*; Average use is 4 units/Pt; 3.3 million N.Am + 3.0 million Europe + 2.0 million Japan; adds $41/unit; FFP now sells for $40/unit and (competitor) Vitex S/D sells for $125/unit; Fresh (used w/in 8 hours) frozen plasma can be stored 1 year. Anticipated FDA approval in Q1/03; Europe in summer '03.

RBCs: *25-31 million units/year WW*; Average use is 2 units/Pt; 10.7 million N.Am + 12.2 million Europe + 3.0 million Japan; adds $45 to $80/unit; RBCs can be stored cold for ≤ 42 days. Anticipated FDA approval in Q2/04; Europe in Q2/04.

It is also noteworthy that, due to more rigorous donor screening, blood testing (up to 12 tests) and leukocyte (white cell) reduction, the actual risk of infection from any transfusion is very low (Hep C, 1:1 million units; HIV, 1:10 million units). The risk of receiving unmatched blood (due to human error) is much higher at 1:12,000. In addition, many blood banks lose money and are under increasing pricing pressure from their customers/competitors, hospitals.

At the end of August, Morgan Stanley issued a bullish report on CERS ($85 target) having managed a $78 million private placement last May as well as the company's IPO in January 1997. At the same time, the company released more Phase 3 platelet data in front of the ASH meeting, beginning December 7. On October 19, we spoke with Jed Gorlin, MD, to assess 1) the likelihood of FDA approval of Intercept-treated platelets and 2) the market's adoption.

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In Phase 3, the Intercept process resulted in the operational equivalent of the loss of over 30 percent of clinically efficacious platelets. More transfusions were required. Specifically, in the pivotal Phase 3 trial of 645 patients (split evenly), there was no SS difference in the primary clinical endpoint of clinically relevant bleeding (4% with Intercept versus 6% untreated, $p = 0.24$); however, in nine secondary efficacy endpoints, treated versus untreated platelets were SS different from each other. For example, the mean number of platelet transfusions were 8.4 in 318 Intercept-treated patients versus 6.2 in 327 untreated controls ($p < 0.001$).

Dr. Gorlin believed that these data should not preclude regulatory approval in the U.S. However, he strongly suggested that both the direct added expense of Intercept treatment *plus* the (implied) expense of 30 percent more transfusions would likely impede market adoption. In contrast, the additional $25 per unit for leukoreduction, unanimously recommended by an FDA advisory Panel last January, cost-effectively lowers fever and adverse immune responses, both of clinical value.

Finally, the company's… *[Comment about Management redacted by author]* …as to antagonize reviewers at an FDA Panel meeting, thereby "snatching defeat from the jaws of success." For example, in early 1997…*[he]*…proposed initiating a Phase 3 trial of treated platelets after having completed testing in only 15 healthy volunteers. The FDA rejected his proposal and demanded Phase 2-type testing in a limited number of patients.

Cerus should become an excellent short opportunity as it progresses towards regulatory approval and market launch.