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UP & DOWN WALL STREET

Question of Immunity

By Kathryn M. Welling

2111 words

1 August 1994

Barron's

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English

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The story you're about to read is true. And in its broad outlines, alas, oft-told. Not even the names have been changed. Maybe its retelling will protect a few innocents.

The company is **Biomune** Systems Inc., of Salt Lake City, whose shares began trading in Nasdaq's smallcap arena only in April, and which now sports a market capitalization in excess of \$130 million. According to its glossy P.R. handout, **Biomune** boasts an exclusive license to research and market "one drug, which may soon lengthen the lives of AIDS and cancer patients, eliminate ulcers and diarrhea, stop the No. 1 killer of infants worldwide, and put an end to a wide range of other difficult and life-threatening diseases. This drug could not only cure you after you become ill, but it could prevent you from getting sick, meaning fewer medical problems and fewer trips to the doctor -- truly, a better approach to living."

Gee whiz, we're all for that. And so, too, evidently, is Ladenburg Thalmann & Co., which signed on as a financial adviser to **Biomune** last September and issued a "buy" on its shares at 6 1/4 in mid-June. That recommendation was "for very aggressive investors seeking extraordinary capital gains potential in a developmental stage biomedical company." And the research report was carefully upfront with several caveats, including that **Biomune** has neither earnings nor potential to generate any before mid-'95 -- and then only if several stages of the drug approval process take place "without any delays."

Nevertheless, the report says, "it is our opinion that substantial upside potential exists if the drug, Immuno-C, tests in accordance with our expectations." And it goes on for 12 more pages, describing the company, the drug and the grotesquely unpleasant to deadly consequences of a host of human afflictions that Immuno-C may potentially cure, going so far as to quantify the "total potential annual demand for **Biomune's** product" at better than \$40 billion -- with a "b" -- worldwide. On a slightly less cosmic plane, the report projects that, in the first full year after **Biomune** wins FDA approval to market Immuno-C, the company will generate earnings of \$25 million, or \$1.42 a share, on revenues of \$97 million -- if it manages to steer the drug through the FDA within 18 months.

That's a tall order, considering that it was only two weeks ago, on July 18, that the company said the FDA had given it the green light to proceed with the final stage of Phase I testing, clinical studies to demonstrate that Immuno-C is tolerated by healthy humans.

Granted, **Biomune's** Immuno-C has been designated an "orphan drug" and, as such, qualifies for so-called fast-track attention from the regulators to the results of its trials. But that's in large measure because **Biomune** has targeted cryptosporidiosis as the first indication for which it's trying to get Immuno-C approved. A protozoan-borne disease, "crypto" is the cause, **Biomune**

estimates, of up to 21% of all cases of gastroenteritis in humans. In healthy individuals, it produces a very unpleasant, but nonetheless self-limiting, bout of diarrhea. But there's no known cure for the disease, and it's frequently deadly when it strikes AIDS patients, infants, the elderly or others with compromised immune systems -- and that explains the FDA's eagerness to look at data on any potential treatments.

Still, the bureaucrats' "fast-track" designations say nothing about the odds that further testing of Immuno-C will produce results that so wow the FDA that it would dramatically alter its pace -- which is akin to that of a snail, even on the "fast track." According to the Pharmaceutical Manufacturers' Association, the average new drug takes -- not the 18 months Ladenburg and **Biomune** itself project for Immuno-C -- but 8 1/2 years to run the FDA gauntlet from Phase I testing in humans to final approval. And, notes a PMA spokesman, the anecdotal evidence is that "fast-track" designation doesn't much change that time frame. What's more, the "average" new drug spends about 3 1/2 years in pre-clinical testing, before it even arrives on the FDA's doorstep.

It has taken Immuno-C, by contrast, well over a decade to get that far. The outgrowth of technology developed at the University of Arizona Animal Science Center in the 'Seventies, various forms of Immuno-C have undergone 11 years of testing in animals. If, like **Biomune** CEO David G. Derrick, you're an optimist, all those years of animal testing make you highly confident that "if we can repeat in humans what we've seen in animals, where we've had eradication rates so statistically high in a single dosage, then the efficacy is clear-cut," and the drug will now virtually sail through the FDA.

If you're not. . . well, any number of things could slow the process, Derrick concedes, from equivocal test results to the FDA deciding that it wants to see the drug tested for efficacy for longer than 90 days or on more than the 50 AIDS patients that **Biomune's** research plan currently contemplates.

Clearly, though, **Biomune** lately has found and struck an optimistic chord with investors, who are currently valuing its roughly 21.5 million fully diluted shares at 6 1/4 apiece. Indeed, not only has the company raised about \$10 million from private placements of preferred shares in the past year, but its fans have bid up the common from 1 5/8 to as high as 7 1/4 (adjusted for a 3-for-1 split in June), no mean feat considering the malaise that the vast majority of drug and biotech issues have suffered over that span.

And it's all the more remarkable considering that in their most recent auditor's report on **Biomune**, dated last Dec. 15, Arthur Andersen & Co. noted that its "revenue generating operating activities are not in place at significant levels," and that it had lost about \$9 million since its inception, and then warned, "these matters raise substantial doubt about the company's ability to continue as a going concern."

That's a worry **Biomune's** management echoed in its most recent quarterly filing with the SEC, although Derrick on Friday told Barron's that with the "about \$9.5 million" of funds it has raised in its recent private placements now in the bank, and "virtually no debt," the company has enough cash to complete its drug development program. Such petty concerns, clearly, have mattered little to investors lately taken with a drug that has been proven, in animals, **Biomune** says, to prolong life, enhance growth, and strengthen existing immune defenses."

What exactly is this drug? **Biomune's** SEC filings say it is "a protein whey concentrate derived from bovine regular milk that contains a high concentration of immunoglobulins that the company believes may assist in fighting various diseases."

It's an outgrowth, Derrick explains, of research begun years ago by an immunologist and vet who

was intrigued by the fact that calves are born with very immature immune systems and must suckle their mothers' colostrum within the first 24-48 hours after birth in order to develop enough immunity to survive for more than a few weeks. That researcher eventually brewed an artificial colostrum, which another company markets as an animal feed supplement.

The same immunoglobulins, or antibodies, in Immuno-C are present in ordinary cows' milk, Derrick explains, but in extremely low concentrations. "What we have is a patented process by which we can screen for these antibodies and concentrate them highly enough that they become very effective when taken orally."

What this means, as Derrick puts it, "is that what we basically have is the immune system of a cow." In other words, establishing the immune-system enhancing benefits that **Biomune** claims for Immuno-C will depend on proving that humans react the same way to cow antibodies that cows do.

But that's not a shoo-in, some checking around the pharmaceutical industry indicates. In the first place, **Biomune** is scarcely the only company trying to wring medicinal antibodies out of milk products. There are at least three others in the running, including a spinoff from Land O'Lakes, the dairy co-op, and another publicly traded outfit, Immucell Corp. The latter's shares are languishing below 2, even though it's been conducting phase I/II clinical trials on its own "orphan" anti-crypto drug, dubbed CryptoGAM, since late 1991.

The first round of Immucell's efficacy testing produced results more equivocal than the company had hoped for, says CEO Thomas Hatch, and Immucell had to go back to the drawing board to find ways to deliver more of its product to the site of the infection in the intestinal tract. The problem, Hatch explains, is "our product comes from milk -- and mother nature digests food products in the stomach. We have to figure out how to get it through the stomach without being degraded by the acids."

Since **Biomune's** product is likewise dairy-based, it stands to reason that when it starts testing its drug for efficacy in humans, it, too, may well run into the same issue.

Hatch points out, though, that his company and **Biomune** are following somewhat divergent paths. "What we do is rely on nature's method of dealing with illness. When you get sick, your body starts producing antibodies against the infectious agent, and over a period of days, as sufficient antibodies are produced, they bind to the pathogens and clear the infection." To help that process along, Hatch explains, Immucell is trying to develop drugs that essentially deliver more of those same antibodies, faster than the human body can produce them.

Immucell's tack is to use vaccines to hyper-immunize dairy cows against particular disease-causing pathogens, so that their milk products will contain very high concentrations of those specific antibodies, and then to derive its drugs from those milk products.

Hatch adds, "I don't know that there is good scientific evidence, though, that these antibodies actually stimulate immunity -- although that's the pitch **Biomune** is making to the public. If things like that worked, we'd all drink a lot more milk than we do to stay healthy."

Concludes Hatch, who studied under one of **Biomune's** founders at Brigham Young University in the mid-'Seventies, "I don't rule out the one in 100 chance that **Biomune** actually has something. But if I were betting, I'd say the other 99% is going to rule."

And that's a bet, it turns out, based on considerably more than the scientific evidence. As Hatch knows -- and anyone else who cares to take the trouble to research **Biomune's** corporate history can discover -- ever since its December 1981 founding as New Age Corp.-- the company's true *raison d'etre* hasn't been shrimp farming in Ecuador or tomato cultivation in Egypt or immunity enhancers or any of the other ventures it's run through. It's been to sell shares -- or, at the least, to

use shares as currency to keep any number of its promoters' ventures afloat.

And who are those promoters? The list is long and their connections colorful, but we will list only one. **Biomune** founder and consultant of long-standing is a Salt Lake City philanthropist, Jack D. Solomon. He owns no **Biomune** shares, according to the company's SEC filings. But a byzantine array of entities in one way or another affiliated with Solomon own more than 35% of its stock. As it happens, way back when -- in 1983 -- the federal district court in Nevada permanently enjoined Solomon from violations of the registration, antifraud, stock ownership reporting and proxy solicitation provisions of the securities laws. Without admitting or denying the charges, Solomon consented to the filing of that injunction rather than fight SEC charges that, as president and chairman of Advanced Patent Technology Inc., he had illegally sold about 8.7 million shares of unregistered stock in purported private placements between 1975 and late 1980 to raise money for APT's purchase of a Las Vegas slot machine route business and other gaming-related enterprises. Over that span, APT's shares climbed from pennies to just under \$10 -- and they subsequently went back to pennies, before being delisted from Nasdaq.

There's a lesson there somewhere.

(See related letter: "Barron's Mailbag: All in the Context" -- Barron's Aug. 29, 1994)

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