GRANT'S
INTEREST RATE OBSERVER®
Vol. 32, No. 17c Two Wall Street, New York, New York 10005 • www.grantspub.com SEPTEMBER 5, 2014

Narcolepsy blues

What do biotech companies do? Why, they appreciate in stock market value. With or without a coherent business plan, even without a revenue stream, they enrich their blissfully ignorant stockholders—or so an Aug. 28 Bloomberg dispatch proposes. "The bottom line," the story says, "is that biotech press releases may be hard to understand, but the results these stocks have put up on the scoreboard are not." Never mind "invest, then investigate"; now comes the simplifying suggestion, "invest."

A bearish analysis of Jazz Pharmaceuticals PLC (JAZZ on the Nasdaq) is the work in progress. Sky-high margins, ultra-low tax rates and blisteringly fast sales growth are the historical facts. Falling margins, a rising tax rate and decelerating sales growth are (or may be) the prospective salient features. With all due respect to the fabled media property of the former mayor of New York, *Grant's* will continue to analyze before it buys, or, as the case may be, sells.

Though Jazz, like Valeant Pharmaceuticals International (*Grant's*, March 7) and Endo International PLC (*Grant's*, July 25), flies a flag of fiscal convenience, this is not mainly a tax inversion story. It is, however, in good part a legal story in which the tax rate could one day play its part. Headquartered in Palo Alto, Calif., Jazz pays taxes in Ireland by dint of its 2012 merger with Dublin-based Azur Pharma Ltd.

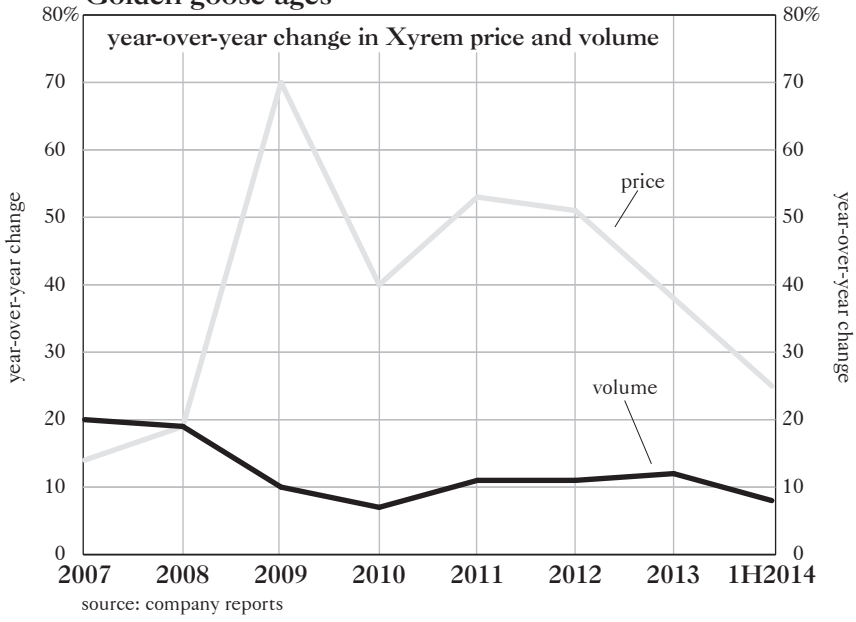
Tax inversions are a hot political topic, of course. Two weeks ago, the Canadian founder of Biovail announced his intention to make them a hotter legal topic. "It's a house of cards," Eugene Melnyk was quoted as saying of Valeant's tax arrangements in an Aug. 23 *Financial Post* story. Melnyk's opinion is informed by the fact that Valeant effected its fiscal escape from the IRS by merging with his own Biovail. If Melnyk's common law, whistle-blowing campaign against Valeant succeeds, Jazz (among other so-called tax inverts) may find itself under a hotter lamp of scrutiny than it has so far had to bear.

In the meantime, the California company with the Gaelic tax rate (19.1% in the latest period, about half of what Uncle Sam would have extracted) is growing like a weed. In the second quarter, year-over-year revenue jumped by 40%, to $291.2 million. Even excluding a spate of recent acquisitions, organic revenue jumped by 30%. Jazz is more than a one-product company, but credit for this singular feat goes largely to a single drug, Xyrem. Used to treat sleep disorder, Xyrem generated second-quarter sales growth of 43%, of which price increases accounted for all but 11 percentage points.

Odd to note, Xyrem is even older than aspirin. It's the brand name for sodium oxybate, the sodium salt of gamma-hydroxybutyrate, a.k.a. "GHB" and "the date rape drug." The Russian chemist Alexander Mikhaylovich Zaytsev first synthesized GHB in 1874, 23 years before the German chemist Felix Hoffmann synthesized aspirin; research into human applications of GHB began in the early 1960s. A depressant, it can cause drowsiness at high doses, death at higher doses.

Sufferers from narcolepsy would

Golden goose ages



source: company reports

seem to need no help falling asleep; it's the bane of their lives that they can't stay awake. Thus, stimulants are what doctors first prescribe to treat the characteristic disruptions in normal patterns of sleep and wakefulness. Xyrem is an alternative therapy. It's administered in extreme cases and/or to patients who respond badly to the side effects of prescribed stimulants. Xyrem works by inducing a good night's sleep to promote daytime wakefulness.

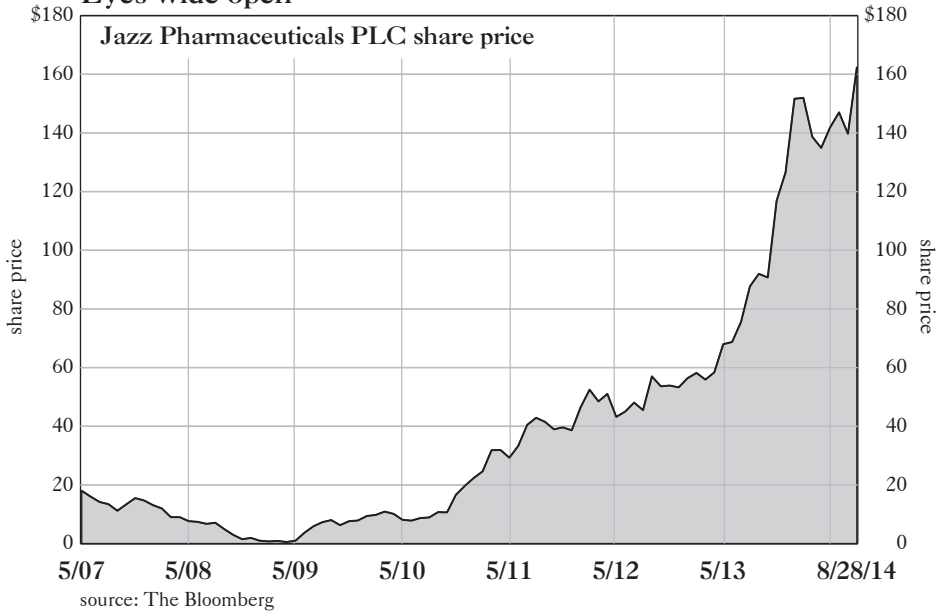
According to the Narcolepsy Network, one in 2,000 Americans is a sufferer, which would imply a potential patient population of 157,000. In the second quarter, Xyrem was prescribed to an average of 11,750 people.

"They, or their insurance companies, pay handsomely for the treatment," observes colleague Evan Lorenz. "A year's worth of medicine costs no less than $65,146. (One would think that a cheaper and more efficacious cure for uncontrollable daytime sleepiness would be just showing patients the pharmacy bill.) Xyrem's profitability is not entirely clear. Jazz doesn't say, and management declined to take my call. However, it appears that Xyrem's gross margins may be knocking on the door of 100% vs. the low-to-mid 60% range for the rest of Jazz's products."

You wipe off your spectacles and stare. Are such profits even possible? Evidently they are. Between 2006 and 2013, Jazz lifted the price for Xyrem by a cool 935%. Jessica Fye, analyst at J.P. Morgan, estimates that Xyrem generates around 80% of the company's earnings per share (our own analysis comports with that figure). How this not-new compound achieved this rarefied earning power value is a story in itself.

"In 2002," Lorenz relates, "Xyrem was granted seven years of patent exclusivity under the U.S. Food and Drug Administration's orphan drug program as there were no similar drugs to treat severe cases of excessive daytime sleepiness and cataplexy (sudden muscle weakness) caused by narcolepsy. Thus, while GHB is classified as a schedule 1 drug (what the U.S. Drug Enforcement Administration terms 'no currently accepted medical use and a high potential for abuse'), sodium oxybate, GHB's sodium salt, is deemed a schedule 3 drug ('drugs with a moderate to low potential for physical and psychological dependence') alongside other molecules like hydrocodone and ketamine. Today, a dozen years after Xyrem was first approved and five years after patent exclusivity should have lapsed, Xyrem is still a de facto orphan drug with no competition."

Eyes wide open



source: The Bloomberg

Not to say that there are no competitors. In 2010, Roxane Laboratories filed what is known as an ANDA (i.e., "abbreviated new drug application") to launch a generic sodium oxybate. Three other generic drug makers subsequently filed ANDAs for the same purpose.

There's competition, too, in the non-generic field. Flamel Technologies SA, a French specialty pharmaceutical company, is working on a branded sodium oxybate with a new formulation that, unlike Xyrem, works with a single dose (patients taking the Jazz medication must set an alarm to take a second dose two-and-a-half to four hours after downing the first one). If the necessary studies pan out, Flamel says it means to submit its product to the FDA for approval by the end of 2016. The drug could be on the market a year later.

The deepest patent moat around Xyrem isn't the molecule itself but the technique for distributing it. Because sodium oxybate is a controlled substance, Jazz is legally bound to devise the means to assure that it doesn't fall into the wrong hands. What's significant about the company's obligatory "risk evaluation and mitigation strategy" (REMS) protocols is that they're patented. No generic manufacturer could copy this procedure—so claims Jazz—without infringing on those patents.

As might be imagined, the generic industry is up in arms over what it views as a competition-thwarting abuse of the business-method patent system (Jazz is far from alone in employing those laws in this fashion). In recent months, petitioners have come before the Patent Trial and Appeal Board of the U.S. Department of Commerce to have Jazz's business method patents invalidated. In an Aug. 7 research note, Irina Rivkind Koffler, the gimlet-eyed analyst at Cantor Fitzgerald, went on record to register her concern that the plaintiffs just might carry their point.

In general, the government's sympathies—notably those of the Federal Trade Commission and the FDA—seem to lie more with the companies outside the REMS moat than within it. As for the DEA, which allocates production quotas for controlled substances, it, too, seems to have turned a slightly less welcoming face to Jazz. Until 2011, the company received 100% of the DEA's annual aggregate quota for the production of sodium oxybate. Since 2012, only a portion of the annual quota has won the green light—just what size portion the DEA won't say unless a Freedom of Information Act request commands it to speak (which request this publication has submitted).

"As to what might happen when generics do reach the market, we can look at a case study from our friend Endo International (*Grant's*, July 25)," Lorenz writes. "In the third quarter 2013, the

first quarter that Lidoderm—Endo's anti-shingles therapy—faced generic competition, Lidoderm revenues fell 37% year-over-year. In the fourth quarter 2013, the second quarter of generic competition, Lidoderm revenue dropped by 87% year-over-year. As Xyrem accounts for approximately four-fifths of Jazz's earnings, the introduction of generic competition could obviously be devastating."

"The generic filers have already attested they don't infringe Jazz's patents and/or that the patents are invalid," a short-seller of Jazz stock—our source asks to go nameless—says. "They could launch today if they got FDA approval of their product. Jazz claims that their REMS stops the FDA from approving this. FDA disagrees. That is being disputed within the agency now."

Besides lawyers, Jazz is deploying new products against the onslaught of the generics. It most especially is seeking drugs for niche diseases, says Bruce C. Cozadd, the company's chairman and CEO. Thus, in January, Jazz committed to spend $125 million up front (milestone payments to follow) for a Phase 2 narcolepsy drug—this one a stimulant—called JZP-110. April brought the closing of the purchase of Gentium S.p.A. for $853 million; Gentium's lead product, Defitelio, treats complications arising during bone marrow transplants (Jazz laid out $75 million in July to purchase the North and South American rights to this drug, with contingency payments to follow). Also on the corporate shopping list is a modified version of Xyrem to compete with the Flamel entry. Our short-selling source contends that nothing will come of this particular therapy, JZP-386, now in pre-clinical trials (it, too, is intended to deliver a full night's sleep in just one dose); anyway, Flamel's drug, which is perhaps two years further along in the wending FDA approval process, has a commanding head start.

To prepare for the post-Xyrem era, whenever it arrives, Jazz is also availing itself of the Federal Reserve's welcoming interest rates. A double-B-rated credit, the company is borrowing at an all-in cost of 3.74%. Especially illustrative of the times is Jazz's 1 7/8% convertible note of Aug. 15, 2021, which trades at 112 $^{7}/_{8}$ to yield 0.03%. From the position of a net cash balance of $86.5 million at year-end 2013, the company showed net debt of $928.2 million at the end of the June quarter.

Just how comfortably, or not, Jazz is managing this encumbrance depends on the accounting metrics one chooses to employ. Do you want the ones in general use or the ones that (as in the cases of Valeant and Endo) management is partial to? There's no small difference.

"Thus," Lorenz observes, "over the last 12 months, Jazz earned $1.25 a share according to its audited financials, $7.16 a share according to management. For the full year 2014, the front office is guiding for GAAP earnings of between $0.47 and $0.90 a share, with non-GAAP earnings between $8 and $8.25 a share. Principal source of the difference lies in costs. Management asks you to exclude acquisition-related expenses, share-based compensation expenses and asset impairments. So by the auditor's lights, the shares are valued at 131 times trailing earnings, according to management's method, at 22.9 times earnings."

The same disparities figure in other financial reckonings. On the one hand, for instance, earnings before interest, taxes, depreciation and amortization totaled $311.8 million over the past 12 months, which fact yields a ratio of net debt to EBITDA of 3:1. This is EBITDA as conventionally defined. EBITDA as management defines it is a different and cheerier story. It totaled $580.5 million over the same 12 months, which delivers a ratio of debt to EBITDA of just 1.6:1.

"Naturally," Lorenz comments, "the businesses that Jazz has acquired are not as profitable as Xyrem so far—it isn't every product that supports annual price increases on the order of 32%. But herein creates a problem for Jazz bulls: they expect the company to retain Xyrem patent protection for the rest of this decade and for the company to acquire hugely profitable, niche drug makers with operating margins of 60% or so, a level of profitability almost four times that recorded by Merck & Co. If we assume that operating expenses are distributed evenly across the Xyrem and non-Xyrem businesses, Jazz's non-Xyrem product lines had a mid-teens operating margin in 2013."

Management may produce its own fancy non-GAAP figures, but it's not clear it believes them. The most recent insider purchase that Lorenz could discover was dated Nov. 11, 2011.

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