

OBESITY REPORT:  
TIPPING THE MARKET  
SCALES WITH BIOTECH &  
MED-TECH REGIMENS

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2010

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Executive Editor: **Michael Harris**  
Managing Editor: **Amanda Lyle**

Senior Vice President/Group Publisher: **Donald R. Johnston**  
Director of Product Management: **Jane Cazzorla**  
Marketing Coordinator: **Sonia Blanco**

Account Representatives: **Bob Sobel, Chris Wiley, Scott Robinson**  
Customer Service: (800) 888-3912 or (404) 262-5476  
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For more information on BioWorld, please contact:

Donald R. Johnston, Sr. VP/Group Publisher  
 BIOWORLD® TODAY  
 AHC Media LLC  
 3525 Piedmont Road  
 Building Six, Suite 400  
 Atlanta, GA 30305 USA  
 Phone: 404-262-5439  
 Fax: 404-262-5510  
 E-mail: [don.johnston@ahcmedia.com](mailto:don.johnston@ahcmedia.com)  
 Websites: [www.bioworld.com](http://www.bioworld.com) and  
[www.medicaldevicedaily.com](http://www.medicaldevicedaily.com)

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— Michael Harris, Executive Editor  
— Amanda Lyle, Managing Editor  
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## An Abstract Analysis: Obesity Treatment and Trends, Today and Tomorrow

### Atlas Shrugged . . . and Slumped Under the Weight of Global Obesity

The world is big and getting bigger in terms of weight, while the drug and medical technology markets that society has become reliant on to develop products for all the major illnesses that afflict it are trying to play catch-up and cope with a half-century of weight gain that threatens to clog society's major veins of productivity and commerce, along with its health.

The weight management market, depending on which products, procedures or services are included, is valued in a range of \$1.4 billion, which represents the current drug market, to \$550 billion, which comprises the "kitchen sink" market, in which everything (from partial stomach excision to hypnotism to diet soda) that purports to address weight issues is included. Unfortunately, biopharma drugs account for a lackluster less-than-1 percent of the total market. Med-tech's contribution is better and increasing, but still in the same basement category of the overall obesity market.

Med-tech and pharma dominate the medically prescribed treatment market for obesity now, although pharma's stint at the top is more by default than a solid R&D aptitude on its part. Medical technology products and services are very effective in treating obesity, but its procedures often are regarded as "for extreme use only" and perceived to be inappropriate for many who likely would opt for an effective drug regimen over a more risky, albeit reliably effective, surgery.

Approximately 80 percent of the hospitals surveyed for a study that was published in *The Journal of the American Medical Association* in January 2008 on the prevalence of

obesity reported an increase in admissions of severely obese patients, reflecting a 22 percent increase from the previous year. Approximately half of those hospitals reported that they purchased new categories of supplies for the treatment of obese patients, including beds, lifts and wheelchairs.

At the moment, surgery is more effective in treating obesity than prescribed pharma drugs, and it has nothing to do with the difference in the number of drug products vs. the number of services and devices. While use of approved pharmaceuticals can reduce excess weight by 5 percent to 10 percent, patients undergoing obesity surgery lose 50 percent to 90 percent of their excess weight.

Pharma's less-than-blockbuster market run is helped by the absence of approved biotech products, but biotech looms to exploit the gaping hole in the treatment market, perhaps as early as late-2010. Whenever the leading crop of biotech applicants gains approval, they are immediately expected to find revenue success, manifesting the market's long-starved appetite and wholesale readiness for safer, more efficacious, easy-to-administer therapeutics.

Although med-tech research advances are hinting at the possibility of some innovative standalone and combination products that could enter the market within the next five years, the advantage of biotech products would seem to be the hope of manipulating cellular activity and "turning off" obesity triggers. Based on encouraging recent results from med-tech, such as the announcement in March 2010 that a team of California Institute of Technology researchers had successfully delivered cancer-fighting RNAi therapies to particular parts of the body via nanotech polymer robots, such

advances in gene therapy could break down that technology's biggest barrier to success – patient site delivery of medication – and hasten the development of many stalled therapeutics in the clinic.

Such potential offers a respite from the inefficacy/side effect dilemma that beleaguers pharma drugs on the market as well as in the clinic, as well as the "drastic treatment" perception that frequently designates medical technology procedures and devices. "Drastic gastric" bariatric surgeries, temporary weight loss prescription drug results and OTC weight loss pills that all but come with an FDA recommendation to carry an extra set of pants, leave skepticism in patients and the door open for the biotechnology industry to ride in on a white horse with that magic pill solution that brings a higher and longer-term efficacy rate, reduces the need for surgeries and carries less ominous side effects than excessive flatulence and irrepressible diarrhea.

There are currently no approved biotech drugs in the space, but they loom, as do the revolutionary medical technologies that may overcome the delivery mechanism challenges that have thwarted advances in administering gene therapy biotech drugs to locations within the body.

There are currently 38 drugs in clinical trials for direct obesity applications, with 19 in late stage trials and three filed for approval. That is not an impressive number, considering the hundreds of clinical trials being conducted for pervasive diseases such as cancer and heart disease; however, it is an indication that the drug development industry is not ignoring the unmet need. Twenty years ago, there was no serious or comparable clinical effort to address the growing indication. That had at least something to do with the perception that being

overweight or obese was commonly regarded as a problem of personal overindulgence that could be sufficiently addressed by personal changes in habit.

This view was reflected by the increase in markets for personal exercise equipment, health club membership enrollment, diet food/beverages and other products relative to shedding weight. However, markets that treated obesity as a medical problem were still largely unaware of or uninterested in the problem of obesity, and that decision has created a wide gap between obesity prevalence and a widely preferred and applied obesity treatment that offers a softer perception of its application than bariatric surgery, the current leading treatment option.

As illogical as it may seem, this problem (just like the weight often does on individuals) crept up on everyone, even though it unfolded right before our eyes. The opportunity to control the proliferation of obesity is still upon those industries, but its 50-year head start has given med-tech and biotech companies that deem to control its further spread an arduous, but far from impossible, task.

### Obesity Can't Be Cured, Resolved or Wished Away by Re-defining it

It would be great if the current debate regarding the assignation of obesity as a disease, condition, factor, symptom or non-issue was actually more meaningful in combating its increasing prevalence. Unfortunately, the inability to define the world's growing problem with increasing body weight does little, if anything, to disrupt the trend itself. No matter how it is defined, it is a big fat problem and a runaway juggernaut affliction that could reverse the increasing average lifespan trend that has characterized the U.S. population over the past 200 years.

Unfortunately, classifying obesity is irrelevant compared to controlling it.

Whether or not the diet industry and the medical treatment community are hyping the situation to drum up business has no bearing on the literal pervasiveness of obesity. Obesity is dangerous and it is crippling society in the workplace, the marketplace and on personal levels, inasmuch as we know it annually causes millions of hours of lost productivity; it drains billions in currency from the global economy in health care-related costs; and it directly causes or contributes to the deaths or infirmity of millions. At the least, it contributes to the most insidious diseases on Earth and impairs the lives of an immeasurable number of people.

So it doesn't matter whether we call it the world's fastest-growing disease or the world's most overhyped condition. New medical and therapeutic technologies are needed to fill the increasing gap between the world's weight gain and the relatively lean combined response of the weight control, health and fitness, and prescription treatment market.

That said, the classification of obesity does bear importance since officially regarding it as a disease is likely to increase public awareness, draw more government resources and initiate relative anti-obesity agendas. The prevalence of obesity has been increasing for over a century and has increased substantially in the past several decades.

Clear and consistent evidence shows that obesity increases the risk of many morbidities and reduces both the quality and the quantity of life. The decision by the U.S. government's Health and Human Services agency to regard it as a disease and cover it so extensively should have ended the debate.

Exercise more, eat less. That is the application for weight control in its simplest form. Unless you are genetically predisposed to being overweight, those words of advice should be

### Cost of Lost Productivity Related to Overweight and Obesity

Workdays lost:	\$39.3 million
Physician office visits:	\$62.7 million
Restricted-activity days:	\$239 million
Bed-days:	\$89.5 million
Source:	Weight-control Information Network.

### Cost of Overweight and Obesity

Total Cost:	\$117 billion
Direct Cost:	\$61 billion
Indirect Cost:	\$56 billion
Source:	Weight-control Information Network.

enough to keep the "World According to BMI" in physically fit frames. But in the real world, the battle of the bulge is a lifelong fight. In the case of most of the U.S. population and approximately a quarter of the global populace, the battle is already a statistical defeat for humankind. To add insult to injury, future generations already are predestined to explode this market into more record echelons of prevalence.

The only thing we seem to agree on is, for some reason, the U.S. population started gaining weight in the 1960s. We presume to attribute it to the TV dinner/drive-through/microwave lifestyle that fascinated the citizenry by saving time in the kitchen and allowing us to devote more time worshipping at the feet of the dubious harbinger of the sedentary life – the television.

Fast-forward to the twenty-first century, in which processed foods, smart devices and leisure-time gadgets constantly emphasize the importance of saving time above all else. That undoubtedly has contributed to create a culture that can encourage obesity, but that may be a theory with holes.

# Obesity Drugs: An Underweight Market Seeks Big Opportunities from a Growing Problem

Obesity is a worldwide problem most obviously seen in developed countries. The Centers for Disease Control and Prevention estimates that more than a third of Americans – about 72 million people – are obese, and another third are overweight.

If current trends continue, 43 percent of U.S. adults will be obese and obesity spending will quadruple to \$344 billion by 2018, according to a study released in late 2009. On the other hand, if obesity rates hold steady, the U.S. would save nearly \$200 billion in health care costs – or about \$820 per adult.

Based on research by Emory University, health care economist Ken Thorpe, executive director of the Partnership to Fight Chronic Disease, the report is the first to estimate obesity prevalence and costs at the state and national level 10 years from now. The report was commissioned by UnitedHealth Foundation, Partnership for Prevention and American Public Health Association in conjunction with their annual America's Health Rankings report.

"At a time when Congress is looking for savings in health care, this data confirms what we already knew: Obesity is where the money is," Thorpe said. "Because obesity is related to the onset of so many other illnesses, stopping the growth of obesity in the U.S. is vital not only to our health – but also to the solvency of our health care system."

The report projects that obesity will comprise 50 percent of the adult population in six states, with an associated increase in health spending linked to obesity of more than \$1,600 per person in each of these "worst" states: Kentucky, Maryland, Mississippi, Ohio, Oklahoma and South Dakota.

Oklahoma is expected to have the highest obesity rate in the country by 2018. The report projects that the state's obesity rate will be 56.1 percent by then, and that obesity-attributable health care spending will be \$1,906 per adult. If obesity levels remain steady, however, it would provide a potential savings of \$1,200 per adult or a savings of more than \$3.2 billion for the state.

According to the report, the obesity rate will stay below 35 percent in only four states and the District of Columbia. Nevertheless, the data shows that obesity-attributable health spending will climb to more than \$800 per person by 2018 in each of these "best" states: Colorado, Connecticut, Massachusetts, Virginia and the District of Columbia. Colorado is estimated to have the lowest obesity rate by 2018 – 29.8 percent. Obesity-attributable health spending in Colorado is expected to be \$864 per adult.

According to the report, Thorpe and colleagues from Emory developed an economic model to estimate the growth of health care costs over time that are attributable to changes in obesity rates. They used nationally representative data on adults to estimate the effect of the increasing prevalence

## Obesity Rankings by State

### Obesity Prevalence, Top Five

Mississippi	32.0%
Alabama	30.3%
Tennessee	30.1%
Louisiana	29.8%
West Virginia	29.5%

### Bottom Five

Hawaii	21.4%
Rhode Island	21.4%
Massachusetts	21.3%
Vermont	21.3%
Connecticut	21.2%
Colorado	18.7%

Source: Centers for Disease Control and Prevention.

## Body Mass Index of U.S. Population

BMI	Description	U.S. Population
20-25	normal	
25-29.9	overweight	
30-39.9	obese	20 million
40-50	morbidly obese	5-10 million
Over 50	superobese	up to 5 million

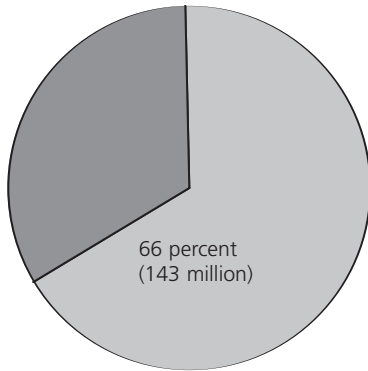
Source: *Biomedical Business & Technology*.

## Aggregate Medical Spending Attributable to Overweight and Obesity by Insurance Status and Data Source, 1996–1998 (US\$ billions)

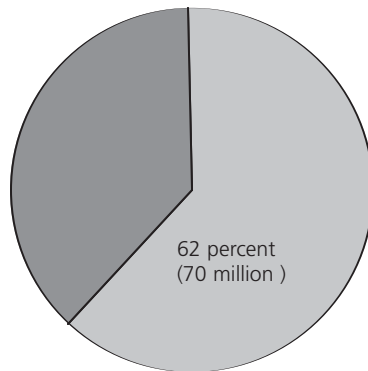
Insurance Category	Overweight and Obesity		Obesity	
	MEPS (1998)	NHA (1998)	MEPS (1998)	NHA (1998)
Out-of-pocket	\$7.1	\$12.8	\$3.8	\$6.9
Private	\$19.8	\$28.1	\$9.5	\$16.1
Medicaid	\$3.7	\$14.1	\$2.7	\$10.7
Medicare	\$20.9	\$23.5	\$10.8	\$13.8
Total	\$51.5	\$78.5	\$26.8	\$47.5

Source: Centers for Disease Control and Prevention.

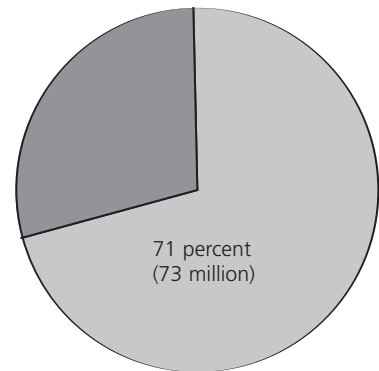
## Percentage of U.S. Adults Who Are Overweight or Obese



**Total**



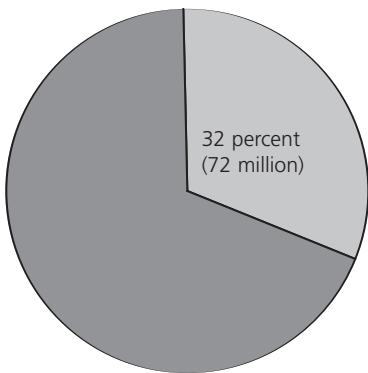
**Women**



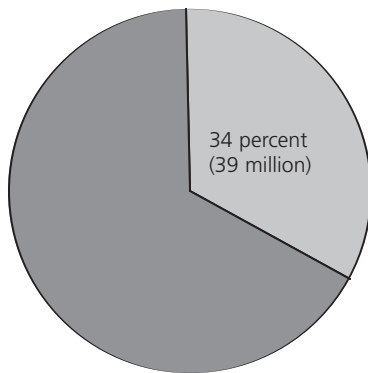
**Men**

Source: Centers for Disease Control and Prevention, National Center for Health Statistics and BioWorld-adjusted-for-2010 data.

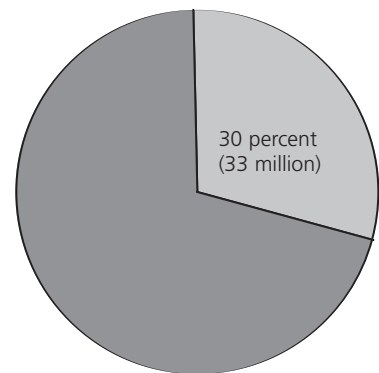
## Percentage of U.S. Adults Who Are Obese



**Total**



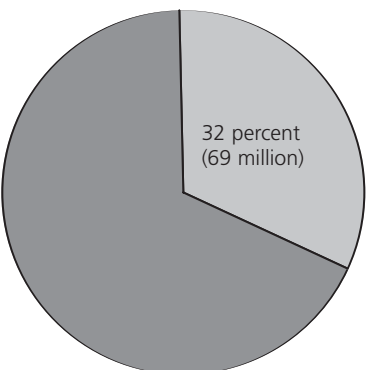
**Women**



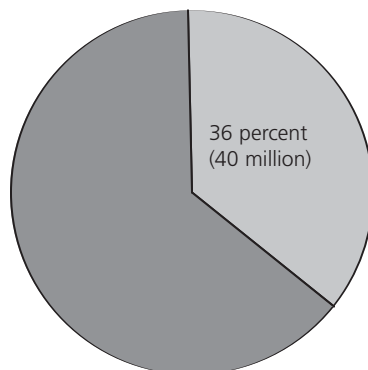
**Men**

Source: Centers for Disease Control and Prevention, National Center for Health Statistics and BioWorld-adjusted-for-2010 data.

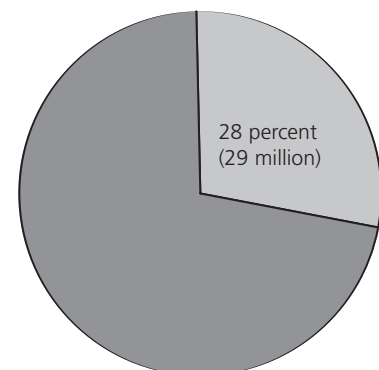
## Percentage of U.S. Adults Who At a Healthy Weight



**Total**



**Women**



**Men**

Source: Centers for Disease Control and Prevention, National Center for Health Statistics and BioWorld-adjusted-for-2010 data.

ic components – as low as one-sixteenth of a pill. That’s a bit more complicated than just cutting a pill in half, Wilson said. Second, Qnexa requires titration, which means the dose changes frequently over the first week – a headache to recreate if you don’t have Qnexa’s titration kit. Third, Wilson continued, there’s “no way” doctors are going to mess with combining obesity drugs that aren’t FDA approved after the debacle surrounding combo drug Fen-Phen. When you put it all together, there are “a couple real pieces of magic that go on here,” Wilson said.

### Vivus Files NDA for Qnexa

On December 29, 2009, Vivus filed a new drug application for obesity drug Qnexa in patients who are obese or overweight with co-morbidities such as hypertension, Type II diabetes, dyslipidemia or central adiposity. Qnexa combines the generic diet drug phentermine with epilepsy drug topiramate. The submission is based on Phase III data in which Qnexa achieved significant percent and categorical weight loss compared to placebo and met regulatory requirements for weight loss products as defined by the current FDA guidance. The drug remained unpartnered at the time of the filing, and a PDUFA date was established for late October 2010.

Vivus president and CEO Leland Wilson predicted that the FDA will convene an advisory panel for Qnexa, considering the safety issues that have plagued other obesity drugs. Wyeth’s Fen-Phen (dexfenfluramine/phentermine) was pulled from the market for safety reasons, while a negative advisory committee meeting blocked Sanofi-Aventis Group’s Acomplia (rimonabant) from U.S. approval.

It will be interesting to see whether the FDA convenes a single advisory panel or multiple panels to review Qnexa, Orexigen Therapeutics Inc.’s obesity drug Contrave (bupropion

SR/naltrexone SR) and Arena Pharmaceuticals Inc.’s obesity drug lorcaserin. Arena submitted its NDA for lorcaserin on Dec. 22, 2009, and Orexigen followed shortly after. At the time of the Qnexa filing, the only meeting of the Endocrinologic and Metabolic Drugs Advisory Committee listed on the FDA’s tentative 2010 schedule is May 26-27.

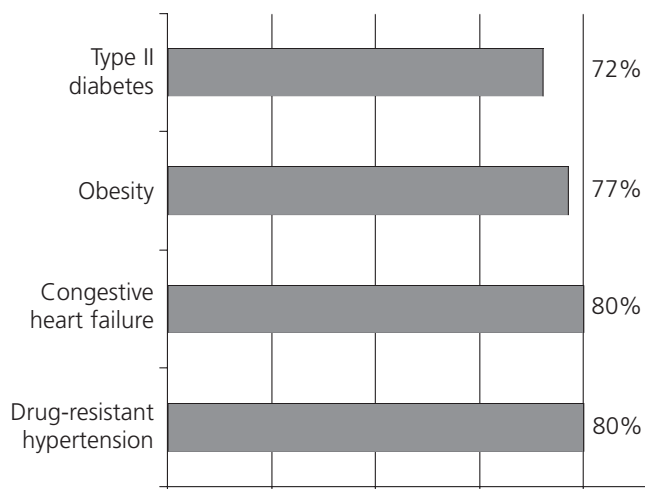
### Vivus Fattens Qnexa Appeal with Phase II Sleep Apnea Data

A week after filing a new drug application for Qnexa in obesity, Vivus presented Phase II data showing the drug also relieved obstructive sleep apnea. JMP Securities analyst Jason Butler wrote in a research note that the news was an “incremental positive” for Vivus. While the sleep apnea data may strengthen Qnexa’s label, the new indication doesn’t meaningfully increase the obesity drug’s market potential, since many sleep apnea patients are obese and thus already would be candidates for the drug. In fact, the overlap between obesity and sleep apnea patients explained why Qnexa worked in both indications. Obese patients may have excess fat in the tissues of their soft palate that

decreases air flow, or they may have abdominal fat pushing up on the lungs and air passages, Vivus president and CEO Leland Wilson told BioWorld. The link between obesity and sleep apnea is well established, but Wilson believes Qnexa has an additional “weight independent” mechanism of action that has yet to be elucidated. In the study, patients receiving Qnexa achieved a rapid improvement in sleep apnea, even before they began to show substantial weight loss, Wilson said.

The randomized, double-blind, placebo-controlled, parallel-group study enrolled 45 obese patients at a single clinical trial site. Qnexa patients achieved a statistically significant 69 percent reduction in apnea events per hour of sleep, dropping from 46 to 14 events while placebo patients dropped from 44 to 27 events ( $p < 0.001$ ). Additionally, Qnexa patients lost 10.2 percent of their body weight compared to 4.3 percent for the placebo group. Qnexa patients also reduced their systolic blood pressure and improved their oxygen saturation. There were no serious adverse events, and the most common side effects were dry mouth, altered taste and sinus infection.

**Percentage of Patients with Obstructive Sleep Apnea**



Source: Vivus Inc., citing Einhorn et al., *Endocrine Prac* 2007; O’Keefe and Patterson, *Obesity Surgery* 2004; Maisel et al., *HFSA* 2007, Wash DC; and Logan et al., *J. Hypertension* 2001.

## Obesity Deals and Data, cont.

**Orexigen Therapeutics Inc.** OREX-003, a sustained-release formulation of zonisamide plus olanzapine, for drug-associated weight gain. Started a Phase IIa trial (10/2/08)

**OSI Pharmaceuticals Inc.** PSN602, an oral dural monoamine reuptake inhibitor and 5-HT1A agonist, for obesity. Started the first-in-human study of PSN602 (6/19/08); Completed a Phase I trial (5/12/09)

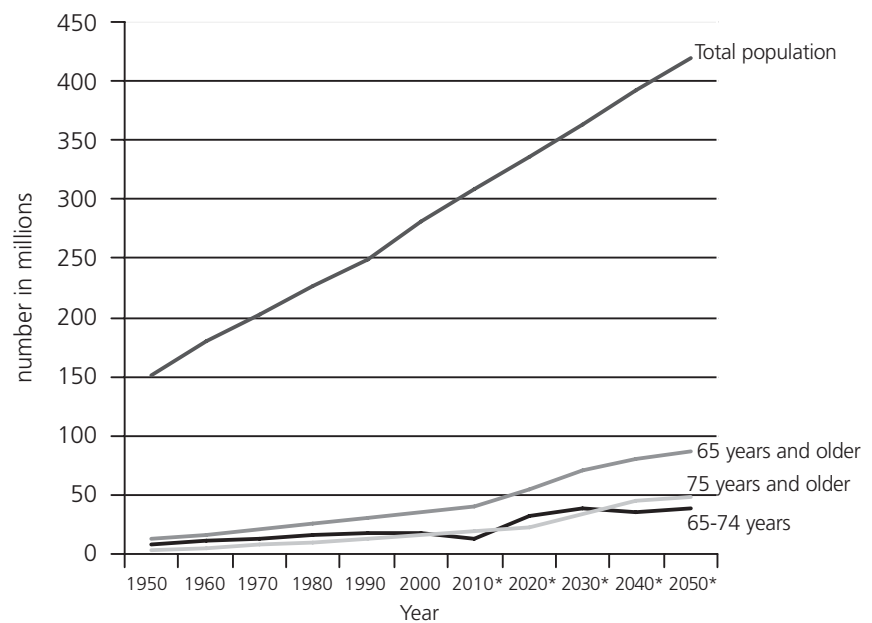
**Pfizer Inc.** CP-945,598, a selective antagonist of the cannabinoid type 1 receptor, for obesity. Pfizer terminated its Phase III development following conversations with the FDA and the failure of other similar obesity drugs (11/6/08)

**Sanofi-Aventis Group** Acomplia (rimonabant) for obesity. Company is complying with an EMEA recommendation to suspend marketing due to potentially higher risks and lower efficacy than originally anticipated (10/23/08)

**Vivus Inc.** Qnexa, a combination phentermine topiramate drug, for obesity. Started a six-month extension study (1/9/08); Completed enrollment in the 28-week EQUATE study with more than 700 patients (3/4); completed enrollment in the EQUIP study (3/27/08); Completed enrollment in the last of three Phase III studies in patients with comorbidities, including hypertension, dyslipidemia, or Type II diabetes (4/22/08); The first of three Phase III trials met its endpoint, demonstrating average weight loss of 9.2% at the full dose and 8.5% at the mid-dose, compared to 1.7% for the placebo group (12/11/08); Phase III data showed a significant control of blood sugar in nondiabetic subjects receiving Qnexa vs. placebo (1/12/09); Phase III data showed a higher weight loss in treated patients than in placebo (9/9/09); The drug's effect was consistent across all levels of body mass index in the EQUIP trial, and a measure of excess body weight loss was 42% in the intent-to-treat population of the CONQUER study (10/26/09)

Source: *BioWorld Insight*.

## Total and Older Population, U.S.: 1950-2050



Note: \*projected

Source: U.S. Census Bureau.

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