MEDIFAST INC
Form 10-K
March 16, 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-K

ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2008

Commission File No. 000-23016

MEDIFAST, INC.

DELAWARE	13-3714405
Incorporation State	Tax Identification number
11445 CRONHILL DRIVE, OWINGS MILLS, MD Principal Office Address	21117

Phone (410) 581-8042

SECURITIES REGISTERED PURSUANT TO SECTION 12(B) OF THE ACT: NONE

SECURITIES REGISTERED PURSUANT TO SECTION 12(G) OF THE ACT:

COMMON STOCK, PAR VALUE $.001 PER SHARE

New York Stock Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes x No ¨

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ¨ No x

The aggregate market value of the voting common equity held by non-affiliates of the registrant as of June 30, 2008, based upon the closing price of $5.26 per share on the New York Stock Exchange on that date, was $64,000,000.

As of March 13, 2009, the Registrant had 14,585,960 shares of Common Stock outstanding.

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PART I

ITEM 1. BUSINESS.

SUMMARY

Medifast, Inc. (the "Company" or "Medifast") is a Delaware corporation, incorporated in 1993. The Company's operations are primarily conducted through five of its wholly owned subsidiaries, Jason Pharmaceuticals, Inc. ("Jason"), Take Shape for Life, Inc. ("TSFL"), Jason Enterprises, Inc., Jason Properties, LLC and Seven Crondall, LLC. The Company is engaged in the production, distribution, and sale of weight management and disease management products and other consumable health and diet products. Medifast, Inc.'s product lines include weight and disease management, meal replacement, and vitamins primarily manufactured in its modern, FDA approved facility in Owings Mills, Maryland.

MARKETS

Throughout the past 30 years, obesity in the United States has dramatically increased. The obesity epidemic shows no signs of slowing down and recently, the condition has worsened among Americans rather than improved. Approximately 1.7 billion people worldwide are overweight; however the percentage of overweight adults is the highest in the United States, with two-thirds of all Americans being overweight or obese.

According to a recent study, "Prevalence of Obesity and Overweight in the United States", published in April 2006 in the Journal of American Medical Association, almost 7 out of 10 adults in the U.S. are overweight or obese, with 60 million (or about thirty percent) American adults suffering from obesity. The obesity epidemic raises concern among Americans because of the implications associated with their health. The most common health conditions associated with obesity are type II diabetes, coronary heart disease, hypertension and stroke, sleep apnea and respiratory problems, gallbladder disease, depression and certain forms of cancer.

The Centers for Disease Control and Prevention show that obesity is not only affects adults, but children and adolescents as well. According to the CDC, the obesity prevalence in children and adolescents has tripled since 1976. Overweight and obesity in children and adolescents increases the risk of health problems such as high blood pressure, high cholesterol and Type 2 Diabetes.

Type 2 Diabetes is expected to increase by 165% between 2000 and 2050 according to a study "Projection of diabetes burden through 2050: impact of change demography and disease prevalence in the U.S.", published 2001 in Diabetes Care. In addition, a study published by the CDC in October 2007 shows how children are now being affected by Type 2 diabetes. Obese children suffering from Type 2 diabetes are at increased risk of suffering significant morbidities in the form of amputations, kidney problems, and blindness.

Obesity is defined as a Body Mass Index (BMI) of 30 kg/m2 or greater, whereas overweight is defined as a BMI ranging between 25 and 30 kg/m2. According to a recent study conducted by the Centers for Disease Control and Prevention in 2006, only four (4) states in the U.S.A. had a prevalence of obesity less than twenty percent (20%). Twenty–two states showed a prevalence equal to or greater than twenty-five percent (25%), and two of those states had a prevalence of obesity equal to or greater than thirty percent (30%).

The primary obesity causing factors are preventable and well known in the United States. These factors are unhealthy diet and physical inactivity. It's estimated that poor nutrition and physical inactivity account for more than 300,000 premature deaths per year in the U.S. According to the United States Department of Health and Human Services, only 25% of adults and less than 25% of teenagers include the suggested 5 or more servings of vegetables and fruits in their daily meal. More than half of American adults fail to engage in the suggested amount of physical activity, and more than 1/3 of young Americans do not engage in regular vigorous physical activity at all.

The United States Department of Human and Health Services states that Americans spend $117 billion in costs associated with overweight and obesity. Direct medical and healthcare costs total $93 billion. The U.S. weight loss market is estimated to be a $55 billion/ year industry. This includes consumer spending on diet foods, health clubs, commercial weight loss centers, low-calorie prepared foods, medically supervised and commercial weight loss programs, diet books, appetite suppressants, artificial sweeteners, diet sodas, videos and cassettes, children's weight loss camps and more.

Distribution Channels

Medifast Direct – In the direct to consumer channel, customers order Medifast product directly through the Company's website, www.choosemedifast.com, or our in-house call center. The product is shipped directly to the customer's house. Customers have access to support from qualified nutritional practitioners and customer care representatives via telephone, e-mail and online chats. Medifast Direct offers a robust online web community and library for support, information and meal planning for weight loss and weight maintenance. This business is driven by an aggressive multi-media customer acquisition strategy that includes print, television, radio, direct mail and web advertising as well as public relations initiatives. The Medifast Direct division focuses on targeted marketing initiatives and providing customer support through its in-house call center and nutrition support teams to better serve its clients. In addition, Medifast also continued to promote its use of leading web technology featuring customized meal planning and community components.

Take Shape for Life™ - Take Shape for Life is a physician led network of independent health coaches who are trained to provide coaching and support to clients on Medifast programs. Health coaches are conduits to give clients the strategies and skills to successfully reach a healthy weight and then provide a road map to empower the individual to take control of their health. Take Shape for Life offers the exclusive BeSlimTM philosophy, which encourages long-term weight maintenance. Take Shape for Life also moves beyond the scope of weight loss to show customers how to achieve optimal health through the balance of body, mind, and finances. Take Shape for Life uses the high quality, medically validated products of Medifast as the platform to launch integrity based lifelong health optimization program.

Program entrants are encouraged to consult with their primary care physician and a Take Shape for Life Health Coach to determine the Medifast program that is right for them. Health Coaches are supported, educated and qualified by The Health Institute, a training group staffed by Medifast professionals. Health Advisors obtain Medifast qualification based upon testing of their knowledge on Medifast products and programs.

Take Shape for Life is a member of the Direct Selling Association (DSA), a national trade association representing over 200 direct selling companies doing business in the United States. To become a member of the DSA Take Shape for Life, like other active DSA member companies, underwent a comprehensive and rigorous one-year company review by DSA legal staff that included a detailed analysis of its company business plan materials. This review is designed to ensure that a company's business practices do not contravene DSA's Code of Ethics. Compliance with the requirements of the Code of Ethics is paramount to become and remain a member in good standing of DSA. Accordingly, Membership in DSA by Take Shape for Life demonstrates its commitment to the highest standards of ethics and a pledge not to engage in any deceptive, unlawful, or unethical business practices. Among those Code of Ethics proscriptions are pyramid schemes or endless chain schemes as defined by federal, state, or local laws. Moreover, Take Shape for Life, like other DSA member companies in good standing, has pledged to provide consumers with accurate and truthful information regarding the price, grade, quality, and performance of the products Take Shape for Life markets.

Medifast Weight Control Centers – The Medifast Weight Control Center is the brick and mortar clinic channel of Medifast located in Texas and Florida. In 2008, the Company opened ten new Medifast Weight Control Centers and had a total of twenty locations in operation at year-end. The centers offer a supervised model and a nationally advertised brand which encourages walk-ins and referrals from other Medifast business channels. In addition to offering a comprehensive Medifast program, the clinics offer customized patient counseling programs, and the Inbody TM composition analysis.

In 2008, the Company began offering the clinic model as a franchise opportunity. On February 18, 2008, the Company announced that it has sold its first franchise of Medifast Weight Control Centers. The Company sold the

rights to open four clinics in the Greater Baltimore Metropolitan Area. The franchisee also has the rights to open four additional Medifast Weight Control Centers in the Baltimore area over the next two years, bringing the total to eight locations. On June 3, 2008 the Company announced that it sold the rights to open four Medifast Weight Control Centers in Southern California and three Medifast Weight Control Centers in Central California to two different local business operators. On October 8, 2008, the Company announced the opening of its first franchise clinic in the Baltimore, MD area. In December 2008, three Medifast Weight Control Center franchise locations opened in Southern California and one location opened in Central California. At December 31, 2008, five franchise locations were operating.

The Company continues to support its controlled label licensee model, Hi-Energy, by providing marketing materials, ads, on-site trainings, fitness programs, nutritional programs and clinical operation materials and forms.

Medifast Physicians –Medifast physicians have implemented the Medifast program within their practice. These physicians carry an inventory of Medifast products and resell them to patients. They also provide appropriate medical monitoring, testing, and support for patients on the program. Management estimates that more than 15,000 physicians nationwide have recommended Medifast as a treatment for their overweight patients since 1980, and over an estimated 1 million patients have used its' products to lose and maintain their weight.

The Company offers an additional in-house support program to assist customers that are consulting their primary care physician. Customers have access to registered dieticians that provide program support and advice via a toll free telephone help line, by e-mail and online chats.

THE MEDIFAST® BRAND

Medifast enriches lives by providing innovative choices for lasting health through products and programs. Medifast is physician recommended and clinically proven offering programs for weight management, weight maintenance and long term health through multiple channels of distribution. Medifast products are high quality, portion controlled meal replacement foods. In recent years, Medifast's core products and programs have continued to expand over a wellness spectrum to include health management products such as those specially formulated for people with diabetes as well as products for women's health, joint health and coronary health.

While all Medifast products are suitable for individuals with type 2 diabetes, Medifast also has a line of products specially designed to meet the needs of people with diabetes – Medifast Plus for Diabetics. Medifast Plus for Diabetics products consist of three delicious, patented shakes that have been certified 'low glycemic' by the Glycemic Research Institute.

Over 40 Medifast products qualify for the FDA's heart healthy claim, "May Reduce the Risk of Heart Disease." In order to make this claim, a product must contain at least 6.25 grams of soy protein per serving and be low in fat, saturated fat, sodium, and cholesterol. Unlike popular fad diets and herbal supplements, Medifast products are a safe, nutritionally balanced choice, offering gender specific formulas containing high protein and low carbohydrates, a soy protein source rather than animal protein source, and vitamin and mineral fortification. It is very difficult to meet the minimum recommended nutritional requirements on a low-calorie diet, but a dieter can easily meet these requirements using the nutrient dense Medifast brand of meal replacement food supplements.

Portion controlled, meal replacement weight management programs are continuing to gain popularity, as consumers search for a safe and effective solution that provides balanced nutrition, quick weight loss and valuable behavior modification education. In addition, consumers are becoming more aware of chronic diseases such as diabetes and coronary health.

Clinical Research Overview

Medifast uses both clinical research studies and retrospective analysis data from its Medifast clinics as the basis of its claim, "clinically proven." The following abstracts include both peer-reviewed research (consisting of prospective controlled clinical trials and retrospective studies) and in-house clinical data (studies 7 & 8).

Study 1
Reference
Haddock CK, Poston WSC, Foreyt JP, DiBartolomeo JJ. "Effectiveness of Medifast supplements combined with obesity pharmacotheraphy: A clinical program evaluation." Eating and Weight Disorders. 13:95-101; 2008.

Purpose
To evaluate the long-term impact of Medifast meal-replacement supplements (MMRS) combined with appetite-suppressant medication (ASM) among participants who received 52 weeks of treatment as part of a medically supervised weight-control program.

Results

Participants who completed 52 weeks of treatment experienced substantial weight losses at 12 (-9.4 + 5.7kg), 24 (-12.0 + 8.1kg), and 52 weeks (12.4 + 9.2kg), and all measures were significantly different from baseline weight ($p<0.001$ for all contrasts) for both true completers (n=324) and for ITT analysis (n=1,351). Fifty percent of patients remained in the program at 24 weeks and nearly 25% were still participating at one year. Results were better than those typically reported for obesity pharmacotherapy in both short- and long-term studies, and also better than those reported for partial meal-replacement programs.

This study was published in the June 2008 issue of Eating and Weight Disorders. Results of this study were presented at the American Society of Bariatric Physicians' annual meeting in May 2007.

Study 2
Reference
Davis LM, Coleman CD, Andersen WS, Cheskin LJ. "The effect of metabolism-boosting beverages on 24-hr energy expenditure." The Open Nutrition Journal. 2:37-41; 2008.

Purpose
To test the effect of thermogenic meal-replacement beverages (TMRB) containing 90 mg of EGCG and 100 mg of caffeine on resting energy expenditure (REE). Thirty adults (19 women, 11 men) were stratified into 3 groups: lean (n=10, BMI 21.5 + 2.1); overweight/obese (OW) (n=10, BMI 29.8 + 2.7); or weight maintainers (WM) (n=10, BMI 28.8 + 4.0). Following an overnight fast, baseline measurements, including REE via indirect calorimetry, were performed. REE was repeated at 30, 60, 90, and 120 minutes after consuming a TMRB. Appetite was assessed via visual analogue scale at baseline, 30 minutes, and 120 minutes after consuming the TMRB.

Results
Mean 24-hour REE was increased 5.9 + 2.5% overall (p=0.000), 5.7 + 3.1% among lean subjects (p=0.0002), 5.3 + 1.4% among OW subjects (p=0.000), and 6.8 + 2.7% among WM subjects (p=0.0007). Appetite was significantly reduced 30 minutes after consuming the TMRB (p=0.0002). TMRBs appear to be a promising weight-control tool.

This study was presented as a poster session at Experimental Biology, 2008.

Study 3
Reference
Cheskin LJ, et al. “Efficacy of meal replacements versus a standard food-based diet for weight loss in type 2 diabetes.” The Diabetes Educator. 34(1):118-127; Jan/Feb 2008.

Purpose
To compare the efficacy of a portion-controlled meal-replacement diet (PCD) to a standard diet (SD) (based on recommendations by the American Diabetes Association) in achieving and maintaining weight loss among 119 obese men and women with type 2 diabetes mellitus.

Results
Using intention-to-treat analyses, weight loss at 34 weeks and weight maintenance at 86 weeks was significantly better on PCD versus SD. Approximately 40% of the PCD participants lost >5% of their initial weight compared with 12% of those on the SD. Significant improvements in biochemical and metabolic measures were observed at 34 weeks in both groups. The retention rate and self-reported ease of adherence in the PCD group were significantly higher throughout the study.

This study was published in the January/February 2008 issue of The Diabetes Educator. The peer-reviewed journal is the official journal of the American Association of Diabetes Educators. The study was also presented at the American Diabetes Association’s 65th Annual Scientific Session, 2005.

Study 4
Reference
Cheskin LJ, et al. “A RCT comparing balanced energy deficit diets with or without meal replacements for weight loss and maintenance among children dieting alone or with a parent.” Johns Hopkins Bloomberg School of Public Health, Center for Human Nutrition, Department of International Health.

Purpose
To compare the safety and efficacy of supplemental Medifast portion-controlled meal replacements (MRs) to a USDA Food Guide Pyramid-based diet. Both weight-loss diets were 20% energy-restricted (~500 kcal deficit). Eighty children (8-15 y.o.), BMI>95th%ile, were screened and randomized to either a MR diet (3 MRs/d during active weight loss and 2 MRs/d during maintenance) or to the food-based diet. Subjects were further randomized to dieting alone or with a parent.

Results
By ITT analysis, dieting alone vs. with a parent or food vs. MR made no difference in weight outcome. However, following initial weight loss (6 mos) and 1 yr maintenance (18 mos), significant benefits were seen in the MR group in BMI%ile (0 mos=98.8 + 1.0, 6 mos=96.6 + 3.2, 18 mos=96.4 + 3.4); body fat (5.9% @ 6 mos, 5.3% @ 18 mos); total cholesterol (6.7% @ 6 mos, 5.6% @ 18 mos); LDL (19.8% @ 6 mos, 7.9% @ 18 mos); and triglycerides (23.6% @ 6 mos, 22.3% @ 18 mos). No significant betweengroup differences, differences in growth rates, or adverse events were observed. Conclusions: Among overweight 8-15 y.o. children, dieting with or without a parent, meal replacements were as safe and effective as a food-based diet for weight loss and maintenance.

This study was presented as a poster session at Experimental Biology, 2007.

Study 5
Reference
Matalon V. “Impaired capacity to lose visceral adipose tissue during weight reduction in obese postmenopausal women with the Trp64Arg B3-adrenoceptor gene variant.” Diabetes. 49:1709-1713; 2000.

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Purpose
To examine the effect of the Trp64Arg gene variant on total and visceral adipose tissue loss, and cardiovascular risk factors in response to weight reduction among 24 obese women (age 57 + 4 yrs) in a 13 + 3 mos weight reduction program of 1,200 kcal with or without the inclusion of Medifast.

Results
Whether women were carriers or noncarriers of the Trp64Arg allele, significant weight loss (-16.4 + 5.0kg vs. -14.1 + 6.2kg, NS) and reductions in body fat (-10.0 + 5.2 vs. -11.5 + 3.9kg, NS) were observed in response to a calorie-restricted program with or without Medifast. Loss of visceral adipose tissue was 43% lower in carriers of the Trp64Arg allele compared with noncarriers (-46 + 27 vs. -81 + 51cm2, p=0.05). The study concluded that older women carrying the Trp64Arg B3-adrenoceptor gene variant have an impaired capacity to lose visceral adipose tissue in response to a calorie-restricted diet.

Study 6
Reference
Matalon V. “An evaluation of weight loss following a carbohydrate and fat restricted diet with appetite suppressant and dietary supplementation.” The Bariatrician. 10-13; 2000.

Purpose
To assess the safety and effectiveness of a weight-loss regimen consisting of a carbohydrate- and fat restricted diet supplemented with an appetite suppressant, a dietary supplement, and a liquid protein drink (Medifast) in an open label trial. Baseline and 6-mos evaluations of body weight (lbs), body fat (%), BMI (kg/m2), lean body mass, water weight, and blood pressure were performed. At 6 mos, statistically significant differences were found for body weight ($p<0.001$), percent body fat ($p<0.001$), BMI ($p<0.001$), lean body mass ($p<0.001$), water weight ($p=0.01$), and body systolic ($p=0.003$) and diastolic ($p<0.001$) blood pressure.

Results
Of 47 patients enrolled, 24 (51%) completed six months using the dietary regimen prescribed. Data was analyzed for all patients who were treated with the diet, as well as for the subset of patients who completed the entire study period. The dietary regimen showed that a carbohydrate- and fat restricted program supplemented by a natural appetite suppressant can lead to progressive weight loss of comparable value to prescribed pharmacologic agents at the time of study. Patients in the study experienced statistically significant decreases in overall body weight, percent body fat, BMI, lean body mass, total body water, and both systolic and diastolic blood pressure.

Study 7
Reference
Crowell MD, Cheskin LJ. “Multicenter evaluation of health benefits and weight loss on the Medifast weight management program.” The Johns Hopkins University School of Medicine.

Purpose
To retrospectively evaluate the efficacy of a medically supervised, protein-supplemented modified program (Medifast) for weight reduction and to evaluate the impact of weight reduction on coexisting health problems.

Results
The results of the study concluded that medically supervised, protein-sparing meal-replacement programs offer a safe and effective means of weight reduction and are accompanied by significant improvements in coexisting health problems. Of samples taken, males lost an average of 67 lbs and females lost an average of 47 lbs during fasting. The study found significant reductions in total cholesterol and triglycerides, systolic and diastolic blood pressure, and normalized blood pressure in hypertensive patients.

Study 8
Reference
Davis LM, Cheskin LJ. “Dietary intervention using Medifast meal replacements in pre-bariatric surgery patients.” Johns Hopkins Weight Management Center; 2006.

Purpose
N=14 severely obese patients—13 females (11 African Americans, 2 Caucasians) and 1 male (Caucasian)—with a mean BMI of 64.14 kg/m2 (range 40.2kg/m2 to 91.7kg/m2) entered a 6-month weight-control program at the Johns Hopkins Weight Management Center. All patients were Medicaid (Priority Partners) recipients. The program provided a comprehensive approach to weight control focused on diet, behavior, and physical activity. Portion-controlled meal replacements (MRs) supplied by Medifast were utilized as part of the dietary-behavior intervention. All subjects met with a licensed dietitian and were prescribed a 1,000-1,200 kcal/day diet plan incorporating up to 6 MRs/day. Only 1 subject chose not to incorporate meal replacements as part of a low-calorie diet plan. The average intake of meal replacements was 2.5-3 per day through the duration of the study.

Results
After 6 months on the program, patients lost an average of 26.73 lbs (-2.86kg/m2) and 6.96% body weight, and reported a high level of satisfaction with their diet plan. Program completers at 1 month were N=13, at 3 months N=12, and 6 months N=10.

A statistical review of patient charts, unpublished data on file. 2006.
Scientific Advisory Board

In September 2008, Medifast announced the formation of its Scientific Advisory Board.

The role of the Board is to continually review the effectiveness, safety, and nutritional benefits of Medifast's products and programs. The team of specialists will also assist in the development of new Meals and supplements, as well as weight-loss approaches for specific medical needs (i.e., patients with heart disease) or lifestyles (vegetarians, etc.).

The work of this cross-disciplinary group builds on Medifast's heritage of medically sound approaches to weight loss, and the incorporation of leading-edge clinical research into the company's products and programs.

Lawrence Cheskin, M.D.
Director of the Johns Hopkins Weight Management Center in Baltimore, MD

Miriam Cohen, M.D., F.A.C.C.