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### Zacks Top Picks in 2024 Within Our Medical Sector

Part One: Top Picks, Medical Sector, Market Capitalization

Part Two: Top Picks, Medical Sector, By # of Analysts Covering the Stock

Part Three: Top Picks, Medical Sector, Largest 1 Month % Change in Current Fiscal Year (F1) EPS Estimate

Presented by:

John Blank, PhD

Zacks Chief Equity Strategist and Economist 04/08/2024



## U.S. Food and Drug Administration (FDA) and its Role in the Pharma Industry - 1

One of the Medical Sector biggest stock groups

### U.S Food and Drug Administration (FDA) and its Role in the Pharmaceutical Industy - 1

### Importance and Role of US FDA in the Pharmaceutical Industry - 1

The US Food and Drug Administration (FDA) stacks up at the TOP among the various Regulatory Institutions that oversee the working of our ever expanding and growing Economy. In order to understand the critical and vital role played by FDA and its various branches in safeguarding public health in US, here is the breakdown of its main responsibilities:

- Ensuring Safety and Efficacy: The FDA regulates a wide range of products, including food, drugs (prescription and over-the-counter), medical devices, cosmetics, and even tobacco products. FDA establishes strict guidelines and measures to conduct thorough testing to ensure these products are safe and effective for their intended use.
- Protecting the Food Supply: From farm to fork, the FDA oversees the safety of our food supply. This includes regulating the appropriate quantities of food additives and their quality, strict monitoring for presence of contaminants, and ensuring proper labeling.
- Advancing Public Health Initiatives: The FDA doesn't just react to potential threats; it actively promotes public health. FDA has put in place systems and process to hasten up the development of safe and effective medical products, It also provides the public with scientifically backed research and health information.
- Combating Public Health Threats: The FDA plays a crucial role in national security by safeguarding the food supply chain from terrorism and ensuring the development of medical products to address public health emergencies.

That is, in essence, the FDA acts as a watchdog, setting and enforcing standards to ensure the safety, quality, and effectiveness of the products we consume and use every day.

Source : www.fda.gov www.ncbi.nlm.nih.gov

### How does the US FDA regulate the Pharmaceutical Industry - 2

The FDA formulates and applies a multi-pronged approach to regulate the "BIG & POWERFUL" Pharmaceutical Industry players, ensuring the safety and effectiveness of drugs throughout their lifecycle. This can be summarized under: Pre-Market Approval (PMA) and Post-Marketing Requirements and Commitments.

### Pre-Market Approval:

- Rigorous Testing: Drug companies must submit an Investigational New Drug (IND) application to the FDA before conducting clinical trials on humans. This application details the drug's properties, proposed uses, and plan for testing. Rigorous clinical trials through various phases (Phase I. II. and III) assess the drug's safety and effectiveness.
- New Drug Application (NDA): After successful clinical trials, a formal NDA is submitted for the FDA's review. This comprehensive document includes all the data on the drug's safety, efficacy, manufacturing process, and proposed labeling. The FDA meticulously examines this data to determine if the drug meets their stringent approval standards.
- Facility Inspections: The FDA inspects manufacturing facilities to ensure they comply with Current Good Manufacturing Practice (CGMP) regulations. These regulations mandate specific quality standards for manufacturing, packaging, and storing drugs to guarantee their purity, potency and safety.

### Post (Drug Approval) Marketing Requirements and Monitoring:

- > Adverse Event Reporting: Even after approval, the FDA closely monitors drugs for any unforeseen safety issues. Manufacturers, doctors, and even patients are required to report adverse events (side effects) associated with the administration and use of the drug.
- Post-Marketing Studies: The FDA may require additional studies after a drug enters the market to gather further data on its long-term effects or effectiveness in broader patient populations.
- Labeling and Marketing Regulations: The FDA regulates how drugs are marketed and labeled. Labels must provide accurate information on dosage, side effects, and potential interactions with other medications. That is, Companies cannot promote/sell a drug/medical formulation which is not approved by the FDA.
- Drug Recalls and Safety Alerts: If the FDA discovers potential safety concerns about an approved drug, they can mandate a recall or issue public warnings to healthcare providers and patients.

By employing this multipronged approach, the FDA strives to ensure that only safe and effective drugs reach the American public.

## U.S. Food and Drug Administration (FDA) and its Role in the Pharma Industry - 2

One of the Medical Sector's biggest groups

### U.S Food and Drug Administration (FDA) and its Role in the Pharmaceutical Industy - 2

### What is the role of FDA in Drug Development and Drug Delivery - 3

The FDA plays a critical role throughout the entire journey of a drug, from its initial development to reaching patients. Here's a breakdown of their involvement in both drug development and delivery:

### **Drug Development:**

- > **Guiding Principles:** The FDA establishes clear guidelines and regulations for drug development. These guidelines outline the steps involved in pre-clinical testing (lab and animal studies) and clinical trials (testing on humans).
- Investigational New Drug (IND) Application: Drug companies seeking to test their new drug on humans must first submit an IND application to the FDA. This application details information about the drug, its proposed use, and the plan for clinical trials. The FDA reviews the IND to ensure the proposed research is ethical and protects the safety of participants.
- Clinical Trial Oversight: While the FDA doesn't directly conduct clinical trials, they oversee the process. They ensure trials are designed appropriately, data is collected accurately, and the rights of participants are protected.
- Data Review and Approval: Once clinical trials are complete, the drug company submits a New Drug Application (NDA) to the FDA. This comprehensive document includes all the data on the drug's safety, effectiveness, manufacturing process, and proposed labeling. The FDA meticulously reviews this data to determine if the drug meets their approval standards for safety and efficacy.

### Drug Delivery:

- Post-Market Monitoring: Even after a drug is approved, the FDA's job isn't done. They continue to monitor the drug for any unforeseen safety issues. Manufacturers, doctors, and even patients are required to report adverse events (side effects) associated with the drug. This allows the FDA to identify any potential problems and take necessary actions, such as issuing warnings or even recalling the drug.
- Risk Management and Labeling: The FDA plays a key role in ensuring proper labeling of medications. They review and approve the labeling information that accompanies the drug, which provides crucial details on dosage, potential side effects, and drug interactions. This information empowers healthcare professionals and patients to make informed decisions about using the medication.
- Manufacturing Facility Inspections: The FDA regularly inspects manufacturing facilities to ensure they comply with Current Good Manufacturing Practice (CGMP) regulations. These regulations mandate specific quality standards for manufacturing, packaging, and storing drugs to guarantee their purity, potency, and safety for patients.

### FDA and its various branches - 4

The FDA accomplishes its critical objectives through its various centers, offices, and institutes, each with specific areas of focus as described below in brief:

- Center for Drug Evaluation and Research (CDER): Responsible for ensuring the safety and effectiveness of human drugs, including prescription and over-the-counter medications, generic drugs, and biosimilars.
- Center for Biologics Evaluation and Research (CBER): Oversees the safety and effectiveness of biological products, including vaccines, blood products, allergenic products, gene therapies, and tissues.
- Center for Devices and Radiological Health (CDRH): Regulates medical devices, including pacemakers, artificial hips, hearing aids, and radiation-emitting devices such as X-ray machines.
- Center for Food Safety and Applied Nutrition (CFSAN): Protects the public health by ensuring the safety and wholesomeness of our food supply, including processed foods, dietary supplements, and cosmetics.
  - Office of Cosmetics and Colors (OCC): Within CFSAN, this office regulates cosmetic products to ensure their safety for consumers.
- Center for Veterinary Medicine (CVM): Ensures the safety and effectiveness of animal drugs, including prescription and over-the-counter medications, food additives, and vaccines for animals.
- National Center for Toxicological Research (NCTR): Conducts research to evaluate the safety of FDA-regulated products.
- Office of Regulatory Affairs (ORA): Conducts inspections of manufacturing facilities, laboratories, and clinical trial sites to ensure compliance with FDA regulations.
- Office of Foods and Dietary Supplements (OFDS): Within CFSAN, this office is responsible for the safety and labeling of all foods, including conventional foods, dietary supplements, and infant formulas.

### Source: www.fda.gov

### www.ncbi.nlm.nih.gov

## Top Medical Stocks by Market Capitalization, # of Analysts, and Largest % Change in F1 Estimates

Take a look through these names for stock picking ideas

Details for the Medical Sector and Industry Names, Top Stocks Lists by Market Capitalisation, Max., # of Analysts Following these Stocks and Largest 1

Month % Change in F1 Estimates

Sector : Medical, Industry : Drugs									
Tickers	Company Name	Mkt., Cap., in \$M	Industry Name						
LLY	Lilly Eli & Co	737318.1	DRUGS						
NVO	Novo-Nordisk As	569871.7	DRUGS						
INI	Johnson & Johns	371733.1	DRUGS						
MRK	Merck & Co Inc	328990.4	DRUGS						
ABBV	Abbvie Inc	313988.8	DRUGS						
UNH	Unitedhealth Gp	423850.0	MEDICAL CARE						
ELV	Elevance Health	117746.2	MEDICAL CARE						
CI	Cigna Group	105560.6	MEDICAL CARE						
HCA	Hca Holdings	87862.1	MEDICAL CARE						
COR	Cencora Inc	49032.7	MEDICAL CARE						
TMO	Thermo Fisher	219635.9	MEDICAL PRODUCTS						
ABT	Abbott Labs	193091.3	MEDICAL PRODUCTS						
ISRG	Intuitive Surg	135902.7	MEDICAL PRODUCTS						
SYK	Stryker Corp	133544.9	MEDICAL PRODUCTS						
MDT	Medtronic	112864.9	MEDICAL PRODUCTS						

Note: List of Top Stocks by Market Capitalisation

Sector : N	ledical, Industry : Medical	Care						
Tickers	Company Name	Mkt., Cap., in \$M	Industry Name					
ALNY	Alnylam Pharma	18996.4	Drugs					
AMGN	Amgen Inc	147066.9	Drugs					
ARGX	Argenx Se-Adr	23631.3	Drugs					
BIIB	Biogen Inc	29999.6	Drugs					
BMRN	Biomarin Pharma	16373.3	Drugs					
AVTR	Avantor Inc	17153.7	Medical Care					
CI	Cigna Group	105560.6	Medical Care					
HCA	Hca Holdings	87862.1	Medical Care					
TDOC	Teladoc Inc	2407.0	Medical Care					
UNH	Unitedhealth Gp	423850.0	Medical Care					
BSX	Boston Scientif	99953.2	Medical Products					
EW	Edwards Lifesci	55991.2	Medical Products					
ISRG	Intuitive Surg	135902.7	Medical Products					
MDT	Medtronic	112864.9	Medical Products					
ZBH	Zimmer Biomet	26712.0	Medical Products					

Note: List of Top Stocks by Max., # of Analysts following these Stocks

Sector : Medical	
Industry Names	
Drugs	
Medical Care	
Medical Products	

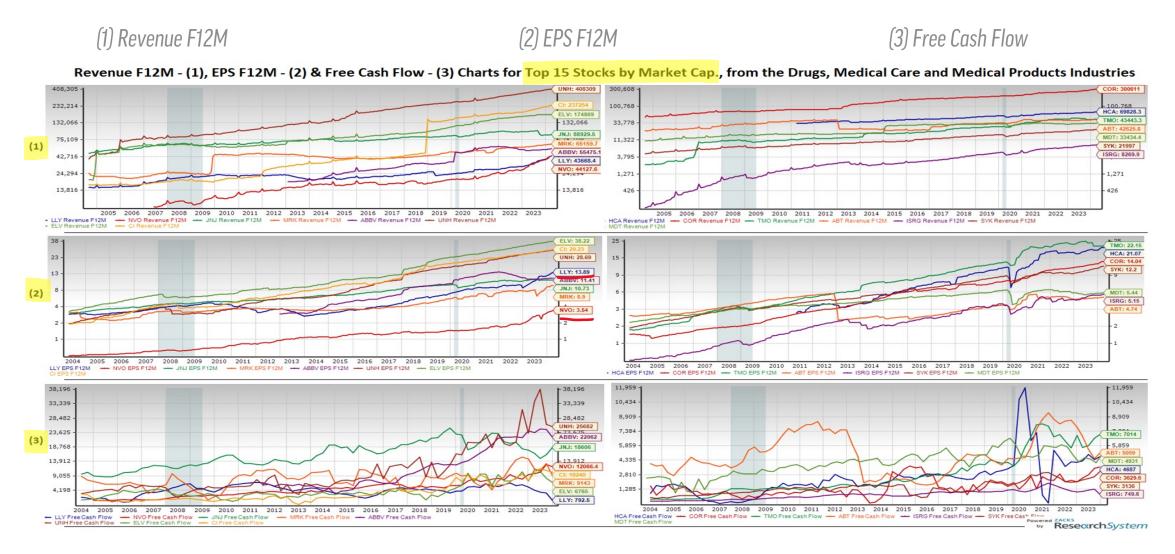
Sector : Medical, Industry : Drugs										
Tickers Company Name Mkt., Cap., in \$M Industry Name										
ANIK	Anika Therapeut	390.3	DRUGS							
SNGX	Soligenix Inc	5.1	DRUGS							
CGEN	Compugen Ltd	210.5	DRUGS							
CNTB	Connect Biophar	117.3	DRUGS							
ZVSA	Zyversa Therap	5.4	DRUGS							
EHAB	Enhabit Inc	551.2	MEDICAL CARE							
GDRX	Goodrx Holdngs	2654.4	MEDICAL CARE							
DMTK	Dermtech Inc	23.5	MEDICAL CARE							
ASTH	Astrana Health	2333.3	MEDICAL CARE							
PGNY	Progyny Inc	3449.9	MEDICAL CARE							
ніті	High Tide Inc	207.0	MEDICAL PRODUCTS							
PAVM	Pavmed Inc	21.2	MEDICAL PRODUCTS							
BWAY	Brainsway Ltd	93.5	MEDICAL PRODUCTS							
PHGE	Biomx Inc	16.1	MEDICAL PRODUCTS							
SNDL	Sndl Inc	578.8	MEDICAL PRODUCTS							

Note: List of Top Stocks by Largest 1 Month % change in F1 Estimate

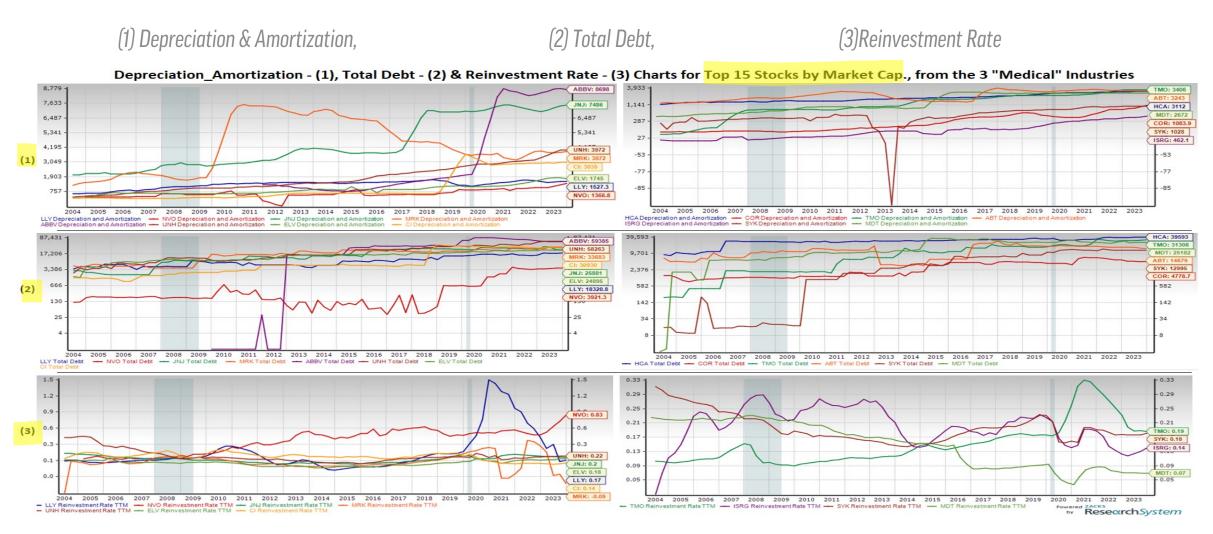
Source: Zacks Investment Research

Part One:
Top Picks
Medical Sector
Market Capitalization

### Top 15 Stocks by Market Capitalization, from Drugs, Medical Care and Medical Products Industries - 1



## Top 15 Stocks by Market Capitalization, from Drugs, Medical Care and Medical Products Industries - 2

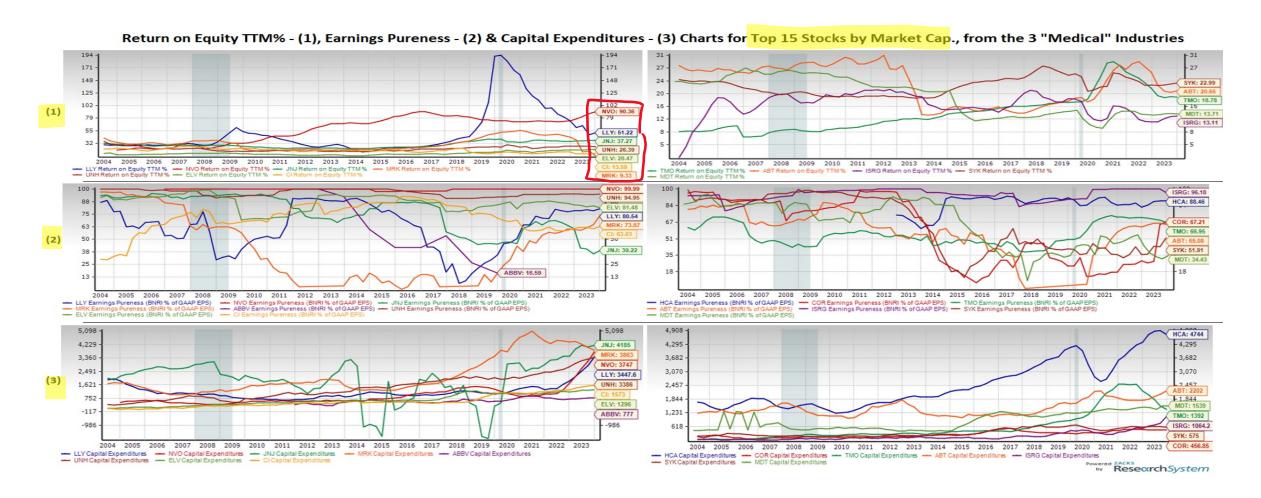


## Top 15 Stocks by Market Capitalization, from Drugs, Medical Care and Medical Products Industries - 3

(1) Return on Equity (TTM%),

(2) Earnings Pureness

(3) Capital Expenditures

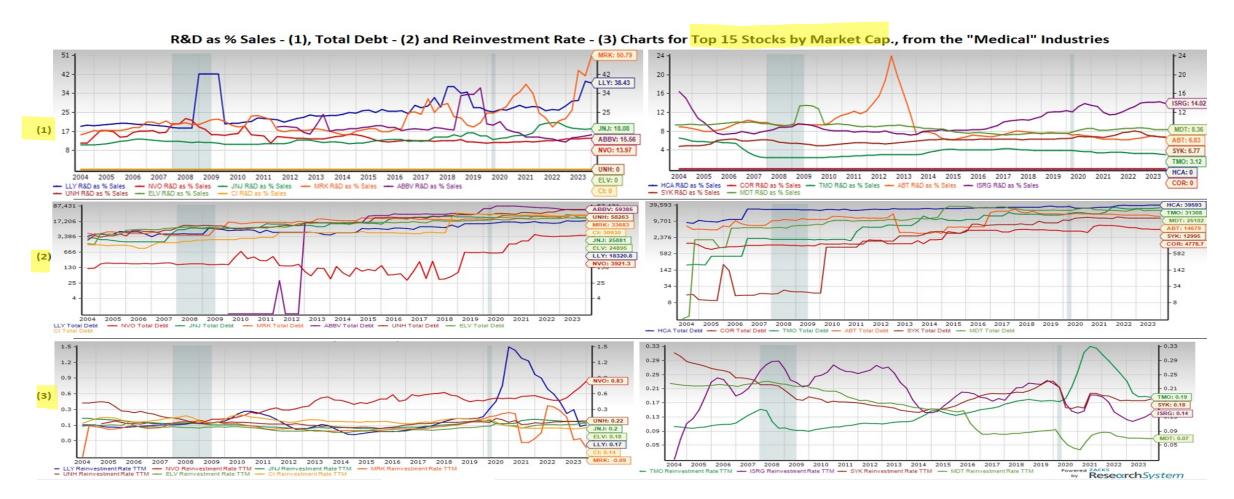


### Top 15 Stocks by Market Capitalization, from Drugs, Medical Care and Medical Products Industries – 4

(1) R&D as % of Sales,

(2) Total Debt,

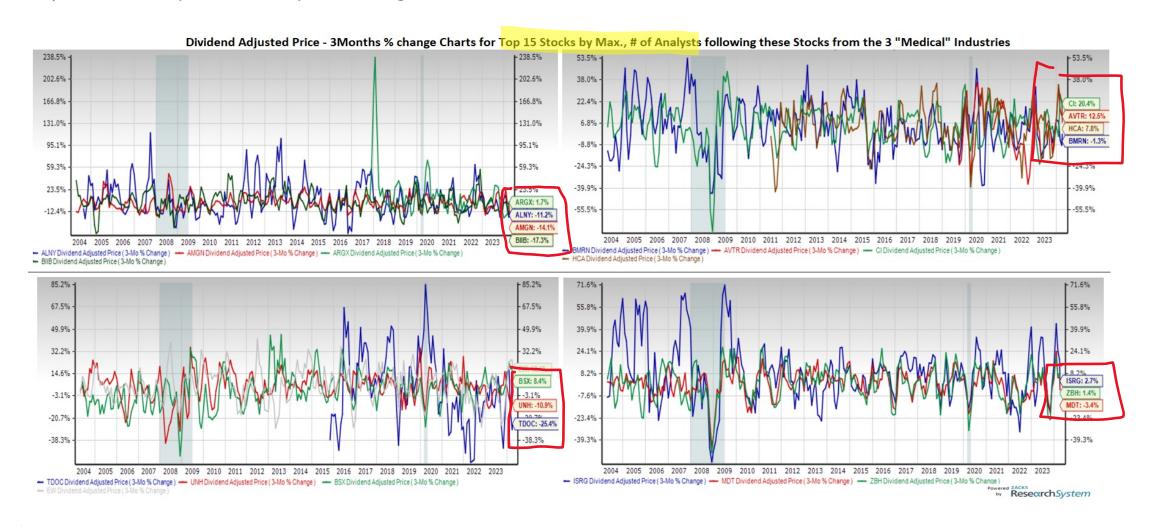
(3) Reinvestment Rate



Part Two:
Top Picks
Medical Sector
By # of Analysts Covering the Stock

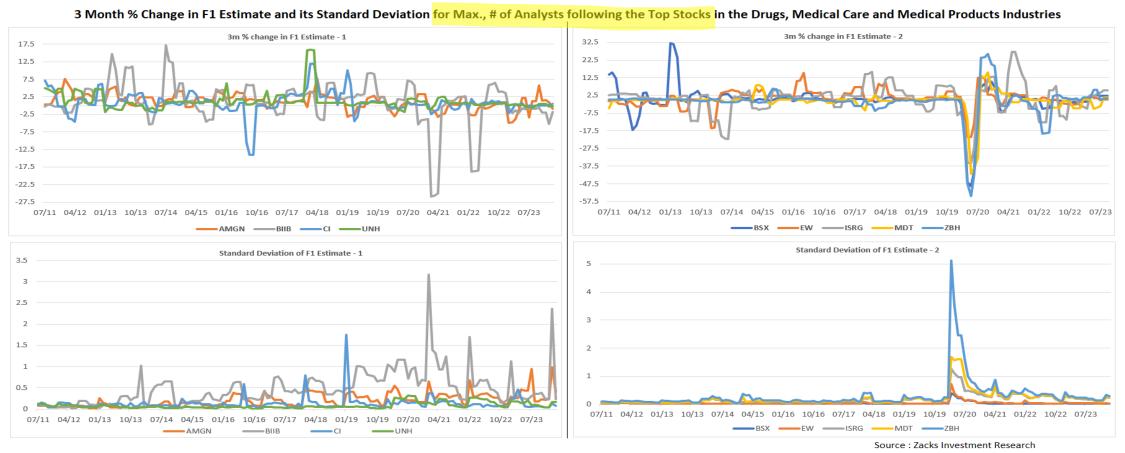
### Dividend Adjusted Price - 3 Month % Change

For Top 15 Stocks --- by Max # of Analysts Following These Stocks --- from the "3" Medical Industries



### 3 Month % Change in F1 Estimate and its Standard Deviation

For Max # of Analysts Following the Top Stocks in the Drugs, Medical Care, and Medical Products Industries



## Price, EPS Consensus, and EPS Surprise Charts for Top 4 and Top 2 Stocks by Max # of Analysts Following These Stocks

From the Drugs and Medical Care Industries



## Price, EPS Consensus, and EPS Surprise Charts for Top 2 and Top 4 Stocks by Max # of Analysts Following These Stocks

From the Medical Care and Medical Products Industries



Part Three: Top Picks

Medical Sector

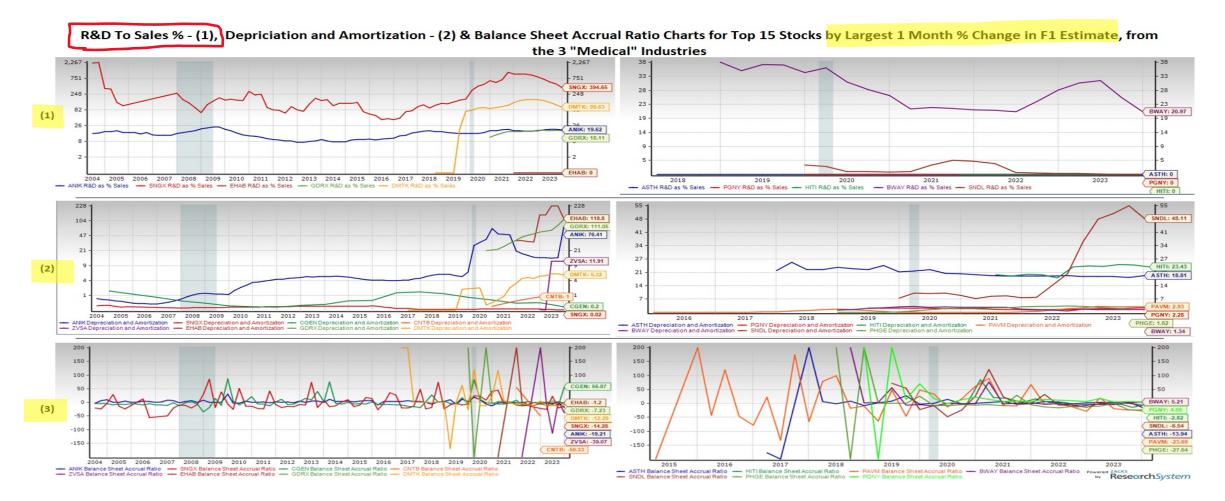
Largest 1 Month % Change in Current Fiscal Year (F1) EPS Estimate

### Top 15 Stocks by Largest 1 Month % Change in F1 Estimate, from Drugs, Medical Care and Medical Products Industries - 1

(1) R&D to Sales (%),

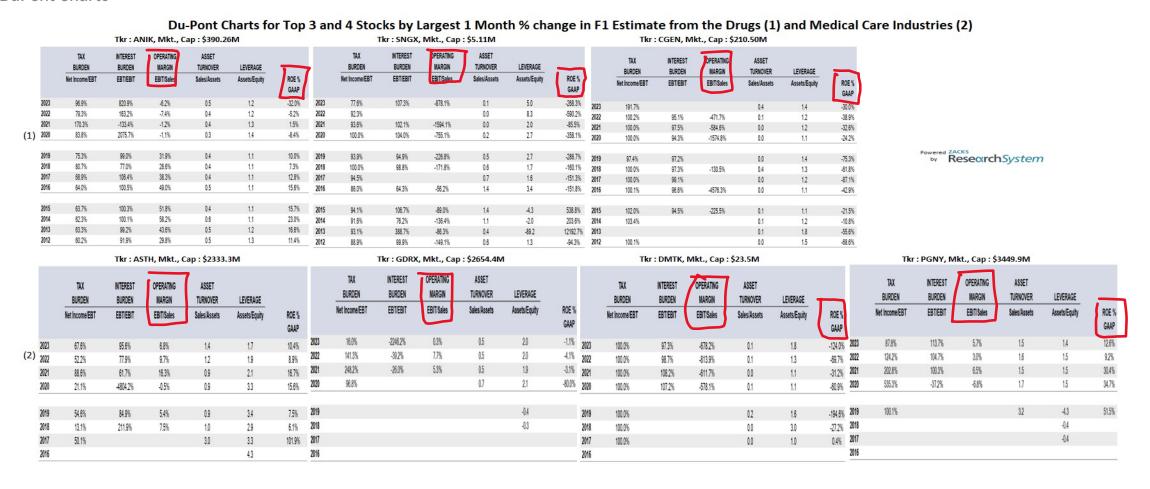
(2) Depreciation and Amortization,

(3) Balance Sheet Accrual Ratio



## Top 3 and 4 Stocks by Largest 1 Month % Change in F1 Estimate, from Drugs, and Medical Care Industries - 2

**DuPont Charts** 



### Top 5 Stocks by Largest 1 Month % Change in F1 Estimate, from the Medical Products Industries - 3

**DuPont Charts** 

### Du-Pont Charts for Top 5 Stocks by Largest 1 Month % change in F1 Estimate from the Medical Products Industry

		Tkr : H	ITI, Mkt., Cap	: \$207.0M				П	cr : PAVM, N					
	BURDEN Net Income/EBT	INTEREST BURDEN EBT/EBIT	OPERATING MARGIN EBIT/Sales	ASSET TURNOVER Sales/Assets	LEVERAGE Assets/Equity	ROE % GAAP		TAX BURDEN Net Income/EBT	INTEREST BURDEN EBT/EBIT	OPERATING MARGIN EBIT/Sales	ASSET TURNOVER Sales/Assets	LEVERAGE Assets/Equity	ROE %	
2023	80.9%	627.2%	-1.6%	1.9	1.7	-25.0%	2023	81.0%	253.5%	-1275.0%	0.1	-4.7	620.2%	
2022	97.3%	310.6%	-6.7%	1.2	1.6	-38.7%	2022	86.2%	223.1%	-12273.5%	0.0	2.2	-263.1%	
2021	98.0%	325.8%	-6.1%	0.9	1.8	-30.4%	2021	89.7%	157.2%	-7140.2%	0.0	1.2	-103.3%	
2020					5.7		2020	95.5%	502.0%		0.0	-0.9	254.0%	Powered ZACKS by Research System
2019					4.3		2019	95.3%	194.9%		0.0	-1.0	281.6%	
2018							2018	98.9%	681.8%		0.0	73.9	-16151.7%	
2017							2017	100.0%	120.4%		0.0	-0.3	197.1%	
2016							2016	100.0%			0.0	1.9	-644.0%	

			Tkr : BWAY,	Mkt., Cap: \$9	3.5M		Tkr: PHGE, Mkt., Cap: \$16.1M													
	TAX BURDEN Net Income/EBT	INTEREST BURDEN EBT/EBIT	OPERATING MARGIN EBIT/Sales	ASSET TURNOVER Salles/Assets	LEVERAGE Assets/Equity	ROE % GAAP		TAX BURDEN Net Income/EBT	INTEREST BURDEN EBT/EBIT	OPERATING MARGIN EBIT/Sales	ASSET TURNOVER Sales/Assets	LEVERAGE Assets/Equity	ROE % GAAP		TAX BURDEN Net Income/EBT	INTEREST BURDEN EBT/EBIT	OPERATING MARGIN EBIT/Sales	ASSET TURNOVER Sales/Assets	LEVERAGE Assets/Equity	ROE % GAAP
2023	106.4%	103.8%	-12.0%	0.5	1.5	-10.0%	2023					2.9		2023	100.4%	116.3%	-16.3%	0.6	1.2	-13.1%
2022	102.4%	102.8%	-46.7%	0.4	1.4	-26.2%	2022	100.2%	103.8%		0.0	1.9	-94.1%	2022	88.2%	-6460.1%	0.8%	0.4	1.2	-22.0%
2021	100.7%	101.0%	-21.4%	0.4	1.3	-10.9%	2021	100.2%	102.0%		0.0	1.4	-71.2%	2021	99.1%	449.6%	-92.1%	0.0	1.1	-18.1%
2020	104.6%	106.6%	-21.9%	0.6	1.7	-26.5%	2020	100.0%	99.4%		0.0	1.1	43.6%	2020	116.2%	231.7%	-146.2%	0.2	2.0	-151.5%
2019	104.3%	116.9%	-36.7%	0.6	1.7	-48.9%	2019	100.0%			0.0	3.1	-82.7%	2019	98.3%			0.2	2.9	-184.2%
2018	103.3%			1.4	6.7	-372.8%	2018					1.1		2018						
2017							2017							2017						
2016							2016							2016						

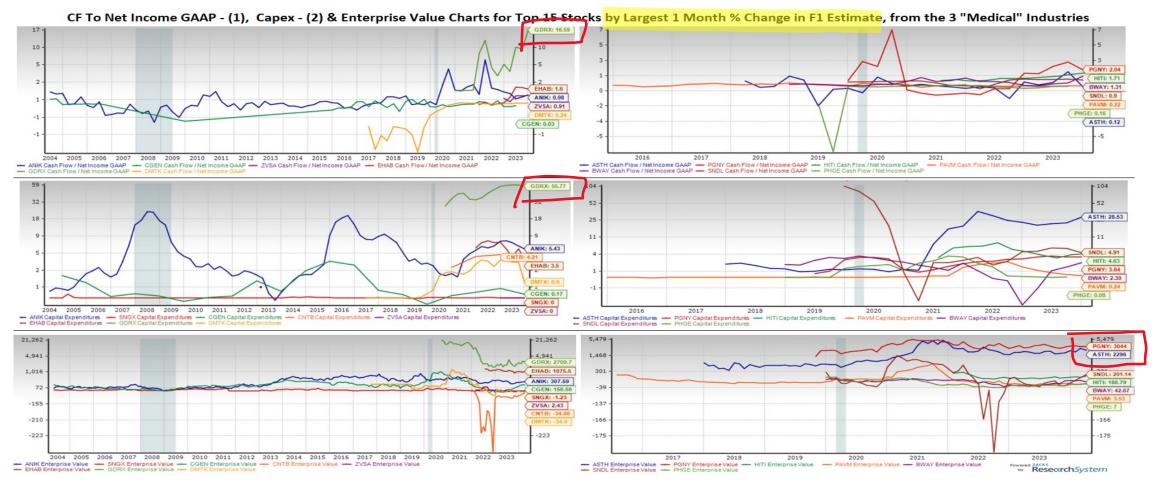
### Top 15 Stocks by Largest 1 Month % Change in F1 Estimate

(1) Cash Flow to Net Income (GAAP),

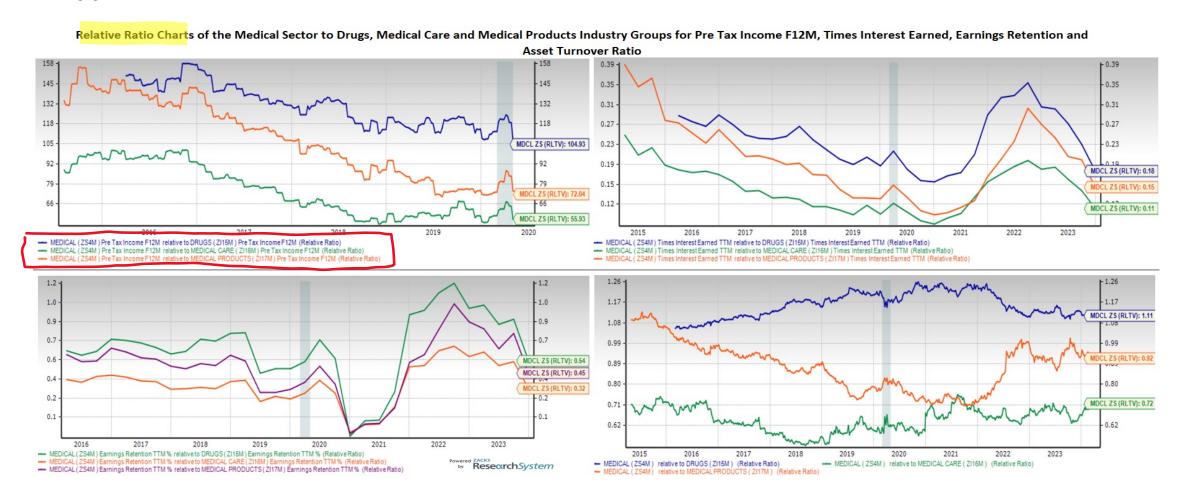
(2) Capex,

(3) Enterprise Value





# Relative Ratio Charts in the Medical Sector for the "3" Industries: For (1) Pre-Tax Income F12M, (2) Times Interest Earned, (3) Earnings Retention and (4) the Asset Turnover Ratio



### Thank You for Attending!

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