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**Analyst Rating: BUY;** long-term market outperformance.

**Stock Information and Data**

ProPhase Labs, a diversified life science company differentiated by experience in consumer markets, is integrating precision medicine and drug development to capitalize on the growth of its diagnostic lab services.

Price (10/15/22): \$10.41

52-Week High: \$15.25

52-Week Low: \$5.35

Avg. Daily Volume: 140,650 shares

Market Capitalization: \$166.6 million

Enterprise Value: \$151.8 million

Shares Outstanding: 16.0 million

Free Float: 12.9 million

Insider Ownership: 20.1%

Institutional Ownership: 13.4%

Short Interest (9/30/22): 2.5%

Revenue (LTM): \$131.2 million

EBITDA (LTM): \$41.4 million

Net Income (LTM): \$26.6 million

Cash: (6/30/22): \$27.5 million

Debt to Capital: 11.1%

Calendar Year: December 31

Headquarters: Garden City, NY

**ProPhase Labs, Inc. (Nasdaq: PRPH)**

**Initial Coverage of ProPhase Labs, Inc.**

- ProPhase Labs has leveraged assets in OTC health products to build a technical and sales infrastructure to support a thriving diagnostic laboratory business. Stronger financials has empowered ProPhase’s expansion with bold initiatives in genomics and biotech. PRPH’s agile management team balances aggressive strategies with pragmatic financial stewardship and a track record of execution – a combination we have rarely seen in a development-stage life science company.
- From January 2021 to March 2022, ProPhase built out a large diagnostics lab with state-of-the-art equipment and custom high-end IT platforms; acquired Nebula Genomics, an innovator in genomic testing, for \$14.6 million; repurchased PRPH shares exceeding \$2 million in value, and returned more than \$9 million in cash via stock dividends to shareholders. Over this period, working capital had increased more than 5 times, from \$9.6 million to \$52.8 million.
- In the latest quarter (Q2-June 30), ProPhase reported revenue of \$29.1 million, up 218% year-over-year on continued strong demand for COVID-19 tests. Net income was \$7.4 million, or \$0.48 per share, compared to net loss of \$1.4 million (\$0.09) for the quarter ended June 30, 2021. Adjusted EBITDA income was \$12.4 million vs. \$0.5 million a year ago.
- Nebula Genomics is the largest direct-to-consumer whole genome sequencing company, being the first to bring the cost of sequencing a human genome below \$300. ProPhase’s goal is to integrate comprehensive genomic testing into its CLIA-certified lab to provide faster turnaround time of results and reduced pricing. ProPhase plans to leverage its distribution in over 40,000 food, drug and mass retail stores, and to open additional channels with businesses and universities.
- ProPhase’s new biopharma subsidiary is pursuing a favorable risk-to-reward strategy for the licensing, development and commercialization of novel drugs and compounds. Equivir and Equivir G, OTC and drug candidates respectively, have demonstrated promising antiviral properties. Linebacker 1 and 2, two small molecule PIM kinase inhibitors, have significant potential as a cancer co-therapy and for other therapeutic indications based on encouraging pre-clinical studies.
- We recommend buying PRPH shares for aggressive growth portfolios. Having established four profitable divisions, ProPhase is swiftly moving to capitalize on intrinsic competitive advantages in business development and customer experience to establish a platform in precision medicine and expand target markets. Higher-profile events over the next 12 months that spotlight ProPhase’s unrecognized intellectual capital may affirm PRPH as a disruptive innovator, leading to a shift in investors’ outlook and a recalibration for valuation multiples.

**Table of Contents**

Page 3: Investment Thesis

Page 5: Comparative Analysis

Page 6: Narratives: Corporate and Markets

Page 8: Management and Strategy

Page 10: Business Overview

- ProPhase Diagnostics
- Nebula Genomics
- ProPhase BioPharma
- TK Supplements
- Pharmaloz Manufacturing

Page 19: Financial Perspective

Page 21: Risk Factors

Page 23: Glossary

Page 25: About Third Stream Research

Page 26: General Disclaimer and Copyright

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ProPhase Labs is a relatively new entrant into the diagnostic laboratory business, having launched operations in late 2020. Accordingly, PRPH's success with COVID-19 testing may be perceived as beginner's luck. We see it differently.

ProPhase fits the classic definition of a disruptive innovator: a challenger entering the low end of a market (diagnostic labs) with an efficient business model. As the firm gains a toehold, it targets additional market segments (whole genome sequencing and biopharma). Rather than inventing breakthrough technologies to improve already good products, *the company innovates to make products and services more accessible and affordable, thereby making them available to a larger population.*

ProPhase at its core is a technology company. Its progressive management team wholeheartedly embraces digital transformation. This is most apparent when we recognize that information technology is an *income generator* for PRPH, not a *cost center* as too many C-level executives at large and small enterprises view it. ProPhase's diagnostic and genomic services operate within an all-encompassing IT umbrella where extensive aggregation of anonymized test data occurs. That is an essential dimension for expanding proprietary research, marketing, and sales, and optimizing interactions with customers and partners.

A small innovator like ProPhase can possess strategic advantages over larger diagnostic lab companies such as Laboratory Corp. of America (NYSE: LH) and Quest Diagnostics (NYSE: DGX). The latter are entrenched competitors with big dollars invested in legacy systems and equipment. ProPhase operates state-of-art analyzers, genome sequencers, and a variety of automation to support higher efficiencies and faster turnaround times in comparison.

Of equal importance is ProPhase's culture and dedication to customer experience. The company's size and agility enables management and employees to quickly respond to changes involving testing and diagnostic analysis, and throughout the supply chain. Rather than battling Labcorp and Quest for market share in drugstore chains, ProPhase Diagnostics succeeds by targeting the edge – independent pharmacies, concierge services, and K-12 schools.

ProPhase's strategy for precision medicine is a variation on the theme. A critical advantage for Nebula Genomics is being the lowest cost provider of whole genome sequencing testing for consumers. Additionally, Nebula benefits from ProPhase's long history in the development, marketing and sales of OTC health products. These distinctions – low cost and experience in consumer markets – raise the probabilities for Nebula to successfully establish its product in brick-and-mortar retailers. ProPhase has a distribution network covering tens of thousands of food, drug and mass retail stores, some of which the company has already engaged in discussions.

Direct-to-consumer genome testing is only one aspect of Nebula. Another is proprietary research, which grows in value with the number of patients tested and proliferation of data compiled and analyzed for integration into Nebula's database and customer reports. ProPhase's goal is to dramatically increase Nebula's sales by decreasing price and turnaround times, and increasing distribution to consumers, businesses, and institutions. An executive at a genome sequencing company recently noted that genomics will be the first line diagnostic across diseases, adding that it is complementary to many existing techniques and only improves the understanding of them.

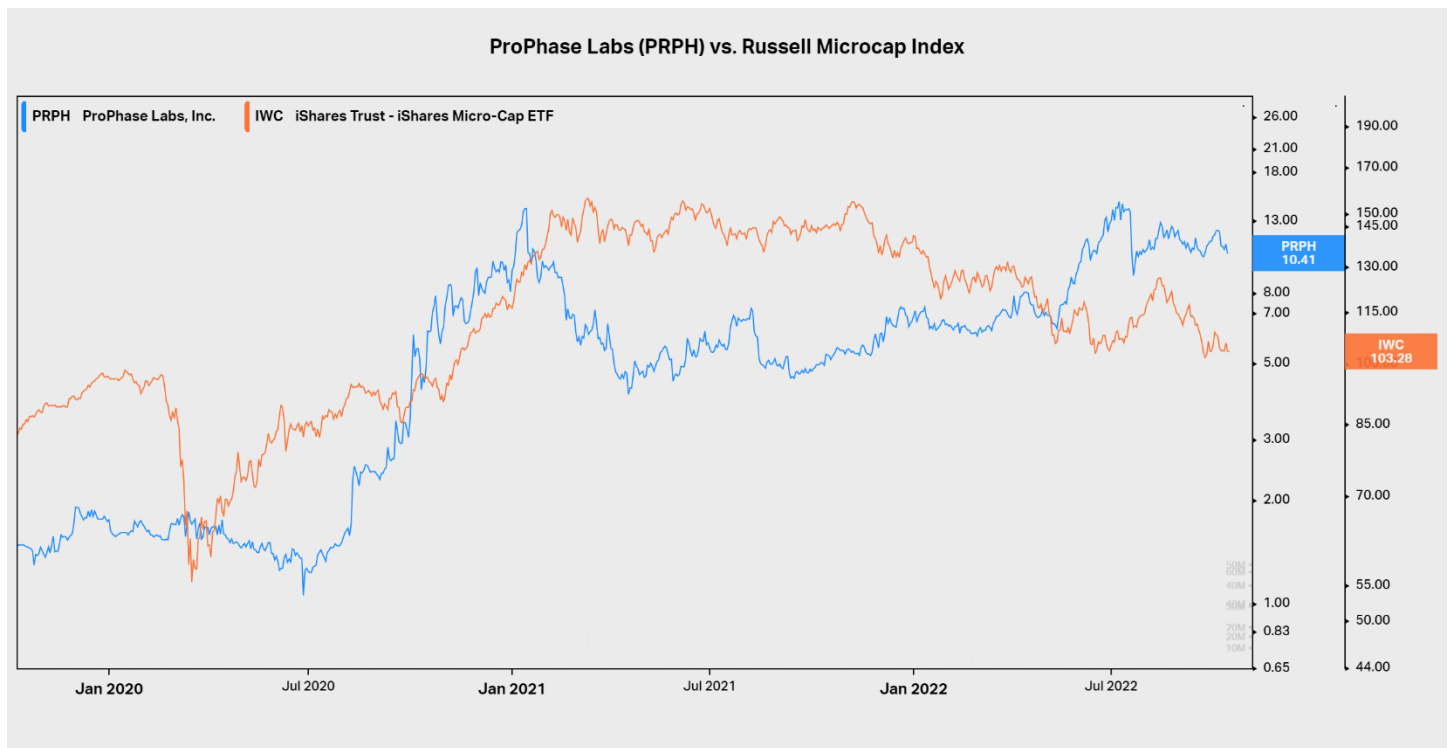
ProPhase's diagnostics, genomics, and biopharma operations are not isolated divisions. Integration of diagnostic and genomic assets are advancing rapidly at the company's Garden City facility. Once ProPhase Diagnostics expands to full clinical services in the first half of 2023, dependence on COVID-19 testing will become less significant. More importantly, PRPH will leverage its growing customer base with a range of traditional and advanced diagnostic tests. Longer term we can envision drug discovery/development in a synthesis with diagnostics and genomics as ProPhase grows into a more complex and integrated organization.

ProPhase ranks high within the top quintile of quantitative metrics for growth, profitability and momentum among more than 1,000 publicly-traded healthcare companies. Still, PRPH is in the lowest quintile for value/sales (EV/S) of the three industries it intersects. At 1.3, ProPhase’s EV/S is dramatically below the average for companies in Biotechnology (7.0), Healthcare Products (4.4), and Information Services (8.7).

ProPhase reported revenue of \$131 million and EDTIDA of \$41.4 million over the last 12 months. That compares to revenue of \$9.9 million and EBITDA of (\$3.7 million) in fiscal 2017. Outstanding shares in both periods were approximately 16 million. Genetic-testing market leader 23andMe (Nasdaq: ME), which reported revenue of \$277 million and an EBITDA loss of (\$255 million) over the last 12 months, currently has 450 million shares outstanding and an EV/S of 3.2.

Over the coming year, we anticipate that technology and distribution partnerships, preclinical and clinical results, and expansion into new markets will reinforce ProPhase as a potentially disruptive innovator. Such advances will also help the company to gain recognition for its intangible assets, which are largely unaccounted for in PRPH’s financial statements or readily acknowledged by investors.

A counter-argument to ProPhase stock being undervalued is that PRPH outperformed approximately 98% of microcap life science companies over the last 12 months. ProPhase also topped the benchmark Russell Microcap Index by a vast margin, 81.0% vs. -29.8%.



Several fundamental value measures, however, indicate that PRPH trades at a significant discount to a variety of peers. Although the shares were lifted by superior revenue and earnings growth over the last two years, the market has yet to recognize ProPhase’s transition to full clinical diagnostic services or the low-cost model for Nebula to bring whole genome sequencing to large numbers of consumers. Biopharma initiatives for antivirals and cancer therapies, promising as they are, will require additional study data before investors begin to account for their potential. Consequently, we believe that ProPhase’s valuation requires greater consideration from two vantage points for investing: PRPH is a rare life science microcap that offers real growth at an attractive value.

COMPARATIVE ANALYSIS

ProPhase operates diverse businesses in diagnostics, genomics research and testing, drug development, health supplements, and manufacturing. Though diagnostic services accounted for ~93% of total revenue for the first six months of 2022, the role of Nebula Genomics is deeply understated based on traditional financial metrics. In fact, we expect that pivotal events for both Nebula (e.g., genome sequencing and retailer partnerships) and ProPhase BioPharma (new pre-clinical data for Equivir and Linebacker) will be important factors, but not the only things, to begin shifting investors' outlook for PRPH and recalibrating valuation multiples.

Peer identification for ProPhase is a challenge because it spans different segments of life sciences. We reviewed companies in three groups – Small-Cap Life Science, Genetic Testing, and Large Diagnostic Labs – to evaluate PRPH relative to a variety of small, mid, and large-cap companies. Our broad latitude may diminish the science of a comparative analysis, but we believe that microcap research is best when it applies some creative discretion.

**ProPhase Labs: Selected Comparisons**

Company/Symbol	Market Cap (\$Millions-LTM)	Revenue (\$Millions-LTM)	Revenue CAGR (3Y FY)	EBITDA (\$Millions-LTM)	EV-Sales (LTM)	EV-EBITDA (LTM)	Gross Margin (LTM)
ProPhase Labs (PRPH)	180.6	131.2	81.9%	41.4	1.3	3.9	57.9%
<b>Small-Cap Life Science</b>							
ChromaDex Corp. (CDXC)	84.3	69.0	28.8%	(27.2)	1.0	n/a	60.8%
Fulcrum Therapeutics (FULC)	421.0	14.5	n/a	(102.1)	18.4	n/a	(414.1%)
Harrow Health (HROW)	326.7	84.3	20.5%	2.5	4.2	n/a	73.3%
<b>Genetic Testing</b>							
23 and Me (ME) <sup>1</sup>	1,291.4	277.1	(14.9%)	(254.9)	3.2	n/a	46.1%
Fulgent Genetics (FLGT) <sup>2</sup>	1,153.7	925.1	259.5%	553.3	0.3	0.5	73.7%
Invitae Corporation (NVTA)	578.7	500.8	46.1%	(735.7)	3.2	n/a	21.9%
<b>Large Diagnostic Labs</b>							
Laboratory Corp. America (LH) <sup>3</sup>	18,514.8	15,715.2	12.5%	3,480.1	1.5	6.3	32.5%
Quest Diagnostics (DGX) <sup>4</sup>	14,306.4	10,582.0	12.7%	2,560.0	1.7	6.1	37.3%

Source: Koyfin, FactSet (as of September 30, 2022)

Notes:

- When asked during the 23andMe quarterly conference about the potential impact from a US recession, its CFO explained that the personal genetic service is a consumer discretionary business. "So, you could imagine that in a severe recession maybe some consumers at the increment choosing not to buy.... We just don't have any experience with a deep recession so we can't say for sure."
- Fulgent Genetics delivered over 1.3 million COVID-19 tests in Q2-2022, down about the 14% year-over-year. The decline in the test volume and the revenue is directly tied to the slowdown in COVID-19 testing, which came down materially relative to Q1 and the highs of 2021.
- Laboratory Corp. of America (Labcorp) reported COVID testing volume and revenue in Q2-2022 was down 45% and 42% respectively compared to last year. COVID testing margins were down due to lower testing demand while the company maintained its capacity. In addition, margins were negatively impacted by COVID testing payer mix. Labcorp expects that its COVID testing in 2022 will decline 50% to 60% year-over-year.
- Quest Diagnostics reported that approximately half of its COVID-19 volume in Q2-2022 came from retail channels. It now has ~6,000 COVID-19 patient access testing sites through retail relationships as well as its own patient service centers. Quest estimates it is performing ~8% of COVID-19 molecular testing in the U.S., up from ~4% in March. The company raised its COVID-19 revenue guidance for full year 2022 to between \$1.15 billion and \$1.30 billion.

Narratives are powerful forces in the lifecycle of a corporation. They are integral for understanding the dynamics of an emerging growth company and the feedback loop of market influences on business operations, strategic decisions, and stock valuation. We have identified several narratives for ProPhase that highlight trends to consider for evaluating PRPH and benchmarking its progress.

*COVID-19 pandemic has slowed, but the health emergency continues:* COVID-19 demonstrates an ability to mutate very quickly and it is highly contagious. In December 2021, after most of the country was vaccinated, it did not prevent an enormous spike in Omicron. Current scientific thinking is that COVID-19 may be with us for many years to come. It is unclear whether there will ever be a high enough vaccination rate to negate COVID-19, in addition to the fact that vaccinations do not prevent all people from catching COVID-19 or spreading COVID-19. Vaccinations primarily reduce the symptoms of COVID-19.

*The coronavirus has morphed in the last two and a half years:* On its way to becoming an endemic disease, the coronavirus has evolved to produce symptoms that look increasingly like those of other seasonal respiratory illnesses, making it difficult to distinguish between COVID-19, respiratory syncytial virus, the flu, the common cold and seasonal allergies. While COVID-19 cases may continue to go through cycles or waves, we can expect a consistent baseline level of COVID-19 testing for the foreseeable future. In addition, new variants that have already surfaced exhibit more evasion of our immune system than any prior version. It is probable that these or other variants with many new, important mutations, will lead to another wave in winter 2022-23.

*Flu season 2022-23 will return to business as usual:* During the 2020-2021 flu season, flu activity was unusually low according to the Centers for Disease Control and Prevention (CDC) thanks to COVID safety measures. However, as social activities, work and travel return to normal, flu cases are expected to climb this fall and winter. Consequently, people will be confused whether they have flu or COVID. In most cases, they will rush to get COVID tested, regardless of which variant happens to be circulating at the time. ProPhase will provide diagnostic testing from a single specimen for both flu and COVID.

*ProPhase is becoming a fully diversified diagnostic company:* ProPhase is aggressively expanding its diagnostic laboratory to offer full clinical services in the first half of 2023. The company will begin testing not only for COVID, but for flu and upper respiratory in Q4 2022. ProPhase is also working to validate tests for monkey pox, although the number of people that are actually going to be tested for monkey pox pales in comparison to the levels being tested for COVID.

*Strong worldwide demand for diagnostic services:* The global clinical laboratory test market is expected to grow at 7.5% CAGR and reach \$320 billion in 2028, according to Brandessence Market Research. Demand is being driven by investments in the diagnosis of target diseases like the cardiovascular disorders, diabetes and tuberculosis.

*Precision medicine introduces new opportunities for ProPhase:* In parallel with the expansion of its diagnostic lab services, ProPhase is building a new genomics laboratory at its Garden City, NY facility to be outfitted with next generation technologies to perform whole genome sequencing and an array of genetic test offerings for both clinical and research purposes. ProPhase will provide high complexity, molecular lab testing for upper respiratory, using full blood, urine and toxicology.

*Low cost of whole genome sequencing opens up direct-to-consumer market:* The Human Genome Project, the initiative to sequence a human genome for the first time, took 13 years, dozens of scientists and research institutions, and cost \$3 billion. Eventually, biotechnology companies started making the sequencing platform more efficient, bringing the cost of genome sequencing to around \$1,000. That is why previous commercial DNA tests used genotyping; by only selecting a few genetic variations of popular interest, these companies slashed prices. Nebula Genomics was the first company able to offer whole genome sequencing, which decodes 100% of a customer's full genome, at \$299 or less. The global direct-to-consumer genetic testing market is projected to reach \$6.3 billion by 2028, according to BIS Research.

*BioPharma strategy raises questions:* ProPhase shares fell 35% between July 20 and July 22, 2022 after an analyst downgraded PRPH in response to the company's press release on the licensing agreement for the Linebacker portfolio. The analyst suggested that because of the imminent decline in COVID testing, ProPhase was diverting from a pure play in diagnostics by pushing into drug development, and genomics also. Our analysis in this report draws a different conclusion about ProPhase's strategic vision.

*ProPhase CEO responds to BioPharma criticism:* Ted Karkus addressed the license agreement for the Linebacker portfolio during an investor conference call in July 2022. He explained that ProPhase had been working for two years with the developer of the compounds, Global Research and Development Group (GRDG), with an enormous amount of due diligence. Karkus also said that a major university did significant pre-clinical research with impressive results. He added that a leading university is very interested to continue working with ProPhase on developing Linebacker. Karkus has a long history in biopharma. ProPhase had a pharmaceutical division under the previous management while he was a major shareholder. He also helped turn around ID Biomedical from near bankruptcy to being sold to GlaxoSmithKline for nearly \$1.5 billion seven years later.

*ProPhase BioPharma initiatives have a positive risk-to-reward:* ProPhase will spend only \$5 million through year-end 2023 on the development of its Equivir and Linebacker platforms. This is budgeted to advance Equivir OTC to market in the first half of 2023, and to underwrite precision-focused pre-clinical studies to demonstrate the potential for Equivir G as an antiviral drug and Linebacker as a cancer co-therapy alongside cancer drugs such as TAXOL. ProPhase BioPharma may be viewed by some observers as an unnecessary risk, as it is the only money-losing PRPH subsidiary. Management has signaled that publication of new pre-clinical data over the coming months will alter this perception.

*ProPhase earnings calls and investor presentations:* CEO Ted Karkus is an enthusiastic presenter who delivers a consistent message and regularly taps the following themes: his record of executing on behalf of shareholders; the lack of execution by 95% of microcap CEOs; acknowledgement of ProPhase executives and employees' achievements, and the importance of terminal value on a per-share basis. Analyst and investor participation reflects a healthy level of engagement, while questions and concerns generally receive direct responses. Separately, we realize how Karkus' comments about the upside for the genomics and biopharma businesses may be regarded by some investors as excessively optimistic given the limited operating histories.

*Wall Street perception of PRPH:* ProPhase is covered by three sell-side analysts at boutique investment banks that specialize in micro and small-cap companies. Two of these firms, ThinkEquity and H.C. Wainwright, have an active relationship with ProPhase; Karkus has made positive references to both in recent investor presentations. Despite the impressive performance by PRPH shares, the company maintains a low profile within the investment community. A primary reason is that ProPhase is mostly self-sufficient and without pressure to raise equity or debt capital, placing it in a minority of small life-science companies nondependent on serial financings.

*Investor sentiment for PRPH:* ProPhase's shareholder base appears to consist of many devoted, long-term investors who have owned PRPH shares for years. Consequently, the 12.9 million share float in PRPH may be tighter than the number suggests. The company's occasional stock dividends are issued to reward the patience of these shareholders. It also reflects the confidence of management in its ability to continue generating positive cash flows and transform new businesses into further growth.

Ted Karkus, CEO and Chairman of the Board of Directors of ProPhase Labs, manages and oversees corporate strategy, product development, sales and marketing, and R&D. Karkus has long focused his career on investing, management consulting and managing emerging growth companies. Karkus financed and advised ID Biomedical, a biotech/vaccine company, when it was valued at approximately \$25 million and near bankruptcy. He successfully persuaded the board of directors into making difficult but necessary changes to management, including the replacement of the CEO, and helped to redirect their strategic focus. Seven years later, the company was sold to GlaxoSmithKline for more than \$1.4 billion.

While advising ID Biomedical, Karkus began a similar decade-long engagement with ProPhase Labs. After years of declining revenues, increasing losses and questionable management activities, the company's direction was in dire need of change, and the shareholders' interests in need of protection. Karkus initiated a highly risky but successful proxy contest in 2009 that led to his position as CEO. After inheriting a severely declining brand portfolio, he restructured the go-to-market strategy for the flagship Cold-EEZE® brand and grew revenues significantly. In 2017, ProPhase Labs sold the Cold-EEZE® brand for \$50 million to Mylan, a multibillion-dollar pharmaceutical company.

He graduated Tufts University with a BS in Psychology and Magna Cum Laude Honors in 1981 and Columbia University School of Business with an MBA in Finance and Beta Gamma Sigma Honors in 1984. He owns a 19.4% stake in PRPH common stock.

Karkus quarterbackes a cohesive management team which skillfully adapts as ProPhase scales operations and continuously improves work-flow processes in all areas of the business. ProPhase also bolstered its finance team in recent months to meet the demands of operational growth, with the hiring of three senior level finance employees who join Chief Accounting Officer Monica Brady.

Alice Lioi, EVP/Co-COO – ProPhase Diagnostics, has more than 18 years of progressive laboratory leadership experience in both clinical and research, including as Director of laboratory operations at ICON and Senior Director of laboratory operations at Quest Diagnostics. Throughout her career, she also managed labs at Brookdale Hospital and Medical Center in New York. While there, she served as the Administrative Director of Clinical and Anatomical Pathology Service and AdvantageCare Physicians, covering 36 medical facilities.

Jason Karkus, EVP/Co-COO – ProPhase Diagnostics, was instrumental in the growth of ProPhase Diagnostics by personally generating tens of millions of dollars in revenue in 2021. He oversees multiple areas including sales, business development, logistics operations, and account management. In addition, he helped develop two elite CLIA-certified labs, build on new technologies and acquisitions, and sustain the company's reputation for quality and innovation.

Sergio Miralles, EVP/Chief Information Officer – ProPhase Diagnostics, is an experienced IT leader with over 12 years of experience in enterprise level cybersecurity, infrastructure, and architecture. He is responsible for ensuring a complete end-to-end technology solution that links the lab customers' patient data via interface to efficiently process and report results. He spearheaded ProPhase's IT system and customer/patient portal, which have proven to be robust, agile, and built to handle instantaneous 100x growth. For the last five years, his primary focus has been on the medical, lab, and diagnostics business.

The trio of Lioi, Jason Karkus and Miralles have established a lab services infrastructure and IT platform that appears to be among the most efficient in the industry.

Sam Beeler, Chief Strategy Officer – ProPhase Precision Medicine, has served in leadership, strategy, and operations roles for Advantage Care Physicians, The Advisory Board, TeamHealth, PivotHealth and more. He is the co-founder of a disruptive clinical research and human performance laboratory with clients that include NFL, NHL, and MLB teams, the United States Navy Seals, and Olympic athletes. Beel has excellent relationships abroad according to Ted Karkus, who suggested in a July 2022 shareholder update that Beel complements ProPhase's initiatives with Group 42 (G42), an





artificial intelligence and cloud computing company based in Abu Dhabi, United Arab Emirates and among the leaders in bringing down the cost of whole genome sequencing.

Kamal Obbad, SVP, Director of Sales and Marketing – ProPhase Precision Medicine, is co-founder of Nebula Genomics. He received his undergraduate degree at Harvard University and did graduate studies in computer science as a Gates-Cambridge Fellow at the University of Cambridge. Prior to founding Nebula, he led teams at Google.

Dr. George Church, Advisory Board – ProPhase Precision Medicine, is co-founder of Nebula Genomics, and is also Professor of Genetics at Harvard Medical School and Director of PersonalGenomes.org. His 1984 Harvard Ph.D. included the first methods for direct genome sequencing, molecular multiplexing and barcoding. His innovations have contributed to nearly all next-generation DNA sequencing methods and companies (CGI-BGI, Life, Illumina, Nanopore). He has co-authored 590 papers and 155 patent publications.

### **Notes on Strategy**

*Diagnostics business created and nurtured organically:* To build ProPhase Diagnostics, management first engaged with companies at every level of the supply chain. After an exhaustive process, they centered their strategy on customer experience for structuring the business and its network of partners and patients. The subsidiary began operations in Q4 2020 and it immediately gained traction in the marketplace. A key to future success is the company's IT portal, which manages patient data and communications, generates valuable research, and supports marketing initiatives.

*Balancing aggressive growth and pragmatic financial stewardship:* ProPhase revenues had averaged just below \$12 million a year from 2017 to 2020 before surging to \$79 million in 2021. For the latest 12 months ended June 30, the company posted revenue of \$131 million. Efficiencies have enabled PRPH to produce nearly 60% gross margins and a 20% profit margin. Revenue growth in diagnostic services has generated substantial cash flow, enabling management to acquire next-generation genomic sequencing capabilities, establish a drug-development subsidiary, and undertake occasional special stock dividends and buybacks. Management has also controlled stock dilution remarkably well for an emerging growth company.

*Agile management with a demonstrated ability to pivot:* Management was tested early when the Health Resources and Services Administration (HRSA) uninsured program for COVID-19 testing was halted due to insufficient funds. More than two-thirds (70%) of the ProPhase Diagnostics' business was HRSA funded at the time. After HRSA stopped accepting claims for COVID-19 testing on March 22, 2022, ProPhase managed to execute a complete pivot within a few weeks. The company's sophisticated IT platform proved essential by rapidly streamlining the process for collecting patient data and insurance information, and enabling ProPhase to confirm the validity of the insurance information.

*Capitalizing on deep roots in biopharma:* Ted Karkus, who has extensive experience in consulting and advising life science companies, wants to build a biopharma division similar to what the company had attempted 15 years ago, but previous management failed to execute on. Drug licensing and development are integral to ProPhase's longer-term strategy, which seeks to capitalize on the lessons learned and resources accumulated over many years.

*Genomics is the connective tissue for diagnostics and biopharma:* ProPhase's diagnostics, genomics, and biopharma initiatives have a natural synergy that will rapidly evolve over the next two years. This provides the company with a strategic advantage as it matures. Genome sequencing and testing can identify disease risk, ancestry, traits and response to medicines, and improve the development of new targeted therapies. Genomics will eventually become the preferred diagnostic across diseases, complementing many existing techniques with greater insight into medical conditions. With that comes the potential to produce greater efficacy, safety, and success in drug development.

## ProPhase Diagnostics

From 2018 to 2020, ProPhase searched for new businesses to develop using the net proceeds from the company's sale of Cold-EEZE® to Mylan for \$50 million in March 2017. ProPhase acquired Confucius Labs in October 2020 for \$2.5 million in cash. The New Jersey-based business was an accredited (CLIA) laboratory approved for a variety of important medical tests, including for COVID-19. Testing started in December 2020 and within weeks demand was surging.

Concurrent with the company's \$43 million stock sales in January 2021, ProPhase opened a 25,000 square foot facility next to its headquarters in Garden City, NY. The CLIA lab featured state-of-the-art technology with a wide range of laboratory testing services for diagnosis, screening and evaluation of diseases, primarily COVID-19 and respiratory pathogen panel molecular tests. ProPhase expanded the lab to approximately 30,000 total square feet in June 2022.

**Clinical laboratory testing**, in general, is performed on whole blood, serum, plasma and other body fluids, such as urine, and specimens such as microbiology samples. Clinical laboratory tests which can be performed by most clinical laboratories are considered routine. Commonly ordered routine tests include blood chemistries, urinalysis, allergy tests and complete blood cell counts. Non-routine tests may require professional 'hands-on' attention from highly-skilled technical personnel, generally require more sophisticated data analysis, technology, equipment or materials, may be performed less frequently than routine tests and may be reimbursed at higher levels than routine tests.

It may not be practical, from a cost-effectiveness or infrastructure perspective, for many integrated delivery networks, accountable care organizations and direct contracting entities, commercial laboratories or physician office laboratories to develop and perform a broad menu of non-routine tests, or to perform low-volume non-routine testing in-house. Such tests generally are outsourced to a clinical testing laboratory which can perform these non-routine tests. Some non-routine tests are advanced. Advanced tests include procedures in the areas of molecular diagnostics (including next-generation sequencing), oncology, neurology, companion diagnostics and non-invasive pre-natal and other germline genetic testing.

ProPhase Diagnostics has emerged as a strong industry competitor in two years on the performance of its COVID-19 testing alone. The company provides fast PCR turnaround, with a daily capacity of tens of thousands of PCR tests between its two labs in NY and NJ. ProPhase concentrated on developing the business primarily in the New York metropolitan region, however, it is currently accelerating efforts to expand its customer base nationwide.

The company initially relied on the HRSA uninsured program, which accounted for approximately 70% of payments. On March 22, 2022, HRSA stopped accepting claims for COVID-19 testing and treatment due to the lack of sufficient funds. Despite requests from the Acting Director of the Office of Management and Budget and the White House Coordinator for COVID-19 Response for additional emergency funding for the uninsured program, emergency funding has not been allocated to the HRSA uninsured program.

ProPhase continues to perform limited testing for uninsured persons and is incurring the accompanying costs. However, as a result of the program's suspension, PRPH did not recognize \$16.7 million of revenues related to COVID-19 testing which was performed for uninsured individuals from March 23, 2022 through June 30, 2022. If funding for the HRSA program is reinstated (an outcome that we believe is unlikely to happen) ProPhase will submit eligible claims for reimbursement to HRSA and record the associated revenues.

Management was tested by these circumstances and handled the challenge extremely well. The company's IT portal was designed to cope with virtually any diagnostic-test scenario, including a shift in HRSA status. A pivot away from the uninsured into a model supported almost entirely by insurance providers and client payers was accomplished within a few weeks, enabling ProPhase to maintain strong revenue levels in the subsequent quarter and beyond. Still, COVID-19 testing is only a gateway for the company.



Diagnostic services revenues are subject to fluctuations in COVID-19 testing demand, which leads to uncertainty quarter to quarter. The demand for COVID-19 tests has been highly volatile, and ProPhase expects it to continue. Demand is primarily driven by the emergence and severity of new variants, which are unpredictable. Also note that three clients of ProPhase Diagnostics accounted for 23.5%, 17.9%, and 11.9%, respectively, of the company's \$79.0 million in revenue for the year ended December 31, 2021

ProPhase Diagnostics currently serves three primary market segments for COVID-19 testing: independent pharmacies, schools, and concierge services in multiple states. The company works closely with partners that assist with logistics, such as patient interface and specimen collection. ProPhase has nurtured strong relationships with these groups due to its emphasis on customer support and fast turnaround, and by expediting payments to partners. Municipal contract wins contributed to extensive expansion and diversification of the customer base over the past year.

### Customer Experience for ProPhase Diagnostics

*Patient Registration → Specimen → Transport to Lab → Diagnostics → Results → IT Portal → Communicate with Patient*

In ProPhase's Q2 2022 earnings call, Ted Karkus addressed a question about a potential drop in COVID-19 testing for the second half of this year. He referenced two specimen collection partners who indicated that school districts will be busy especially in the fourth quarter. ProPhase was already ramping up to meet the demand. In Q4 2022, ProPhase will be testing not only for COVID, but for flu and upper respiratory, which will be useful this winter since people will be uncertain whether they have flu or COVID and will likely rush to get COVID tested, regardless of the variants occurring at that time. ProPhase provide diagnostic testing from a single specimen for both flu and COVID.

Importantly, ProPhase is aggressively expanding its diagnostic laboratory, to begin offering a broader menu of clinical services in early 2023. The company is already working to validate tests for monkey pox, although the number of people that are actually going to be tested for monkey pox pales in comparison to the levels being tested for COVID.

In parallel, PRPH is building out a genomics lab, which is anticipated to be operational in Q1 2023. This positions ProPhase as a fully diversified diagnostic company, providing high complexity, molecular lab testing for upper respiratory, full blood, urine and toxicology, and a full array of diagnostic genomics testing. Additionally, management recently said it is actively looking at a potential acquisition of a small clinical lab that will accelerate its efforts.

In anticipation of the rollout of diversified diagnostic testing services, ProPhase is targeting independent pharmacies nationwide. Management has gained valuable experience with this market segment through COVID testing, and it intends to expand services across the United States by leveraging industry relationships.

The independent community pharmacy represents a \$67.1 billion marketplace, according to the 2021 version of the NCPA Digest, published by The National Community Pharmacists Association and Cardinal Health. It reports that 57% of independent pharmacies serve communities that rank high or very high on the CDC's Social Vulnerability Index. As of late December 2021, pharmacies have delivered nearly 200 million doses of COVID-19 vaccine, according to the CDC.

ProPhase's COVID-19 testing has been the growth engine for revenue and earnings since late 2020. But steps taken by the company ensure it will not be dependent on COVID-19 testing beyond mid-2023. ProPhase's transition into a full-service diagnostics firm is well underway, though some volatility in financial performance over the next two to three quarters is possible. We believe that any bumps in revenue will be short lived however and not deter from the company's long-term trajectory for growth in diagnostics and genomics.

## Nebula Genomics

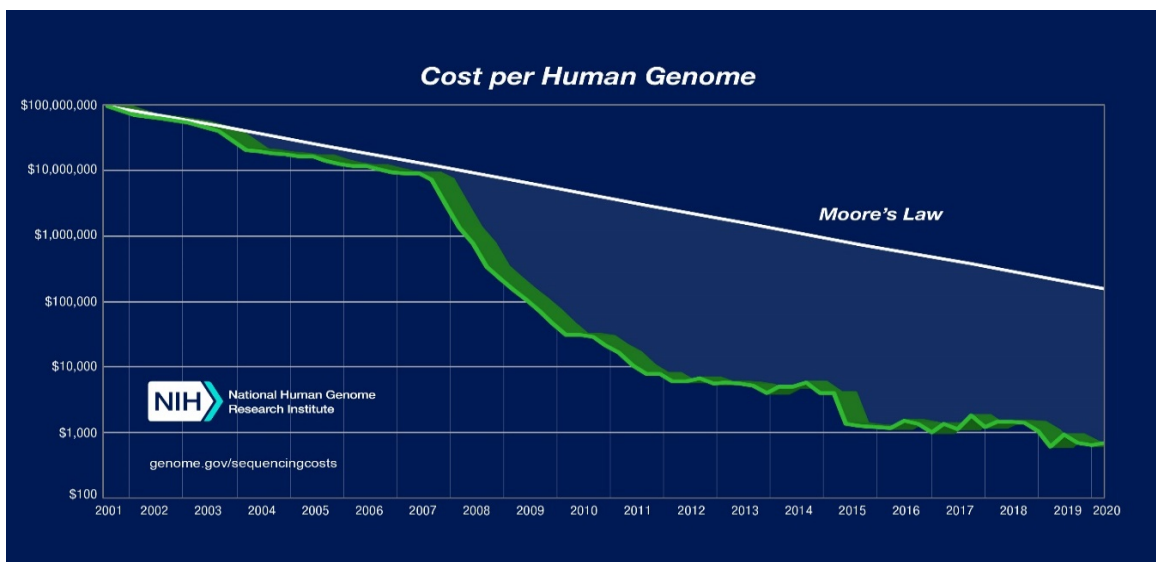
On August 10, 2021, ProPhase acquired Nebula Genomics, Inc., a privately owned personal genomics company, in a cash and stock deal valued at \$14.6 million. Nebula was the first company to bring the cost of sequencing a human genome below \$300 and subsequently became a leader in direct-to-consumer Whole Genome Sequencing (WGS). WGS is a genetic testing technology that obtains comprehensive data on every gene and all chromosomes in a person’s DNA. It can be used to examine ancestry, health, diet, rare gene mutations and rare diseases.

Nebula evolved from the innovations of Harvard University professor and genomics expert George Church Ph.D. He pioneered the development of multiple DNA sequencing methods, including molecular multiplexing approaches that enable next-generation DNA sequencing as well as nanopore sequencing. Nebula had been implementing large-scale human genome sequencing to advance the understanding of the causes of diseases. Church now serves as the founding member of ProPhase Precision Medicine’s scientific advisory board.

Nebula positions ProPhase among the leaders in WGS by providing access to affordable and secure personalized genetic testing. ProPhase is currently building a new genomics laboratory at its Garden City facility to be outfitted with next generation sequencing to perform whole genome sequencing and an array of genetic test offerings for both clinical and research purposes. To evaluate Nebula’s business model, it is useful to have a rudimentary understanding of whole genome sequencing technologies and its economics.

**Whole genome sequencing** is a next generation sequencing technology that takes a different approach than genotyping methods. Instead of selecting specific variants beforehand, whole genome sequencing decodes nearly 100% of an individual’s DNA and can be used to identify previously unknown variants. Genotyping is often thought of as searching for known variants while whole genome sequencing determines the order of your base pairs assuming no prior knowledge. It reads all 3 billion base pairs to report your entire genetic information. Additional companies also promoted whole exome sequencing, a sequencing machine between genotyping and whole genome sequencing in terms of price and comprehensiveness. Exome sequencing decodes the protein-coding genes in the genome. This is about 60 million base pairs, or 1% of the human genome. Before whole genome sequencing, these platforms offered affordable means to get more information than genotyping offered at around \$300.

Automated high-throughput sequencers have increased the speed and reduced the cost of sequencing, making it possible to offer whole genome sequencing, including interpretation, to consumers for less than \$1,000.



The logistics of whole genome sequencing, where it is performed and at what price, is the most challenging part of the process for ProPhase. Illumina (Nasdaq: ILMN) currently has a virtual monopoly on next-generation genome sequencing, controlling 80% market share globally. Pricing for genome sequencing is quoted by Illumina at \$600 today, which is too high for anyone competing in the direct-to-consumer market in the United States. But prices are in fact more complicated than a simple flat rate.

Throughput and cost depend on number of samples and Gigabase per sample (Gb, a unit of measurement used to help designate the length of DNA; one gigabase is equal to 1 billion bases) within the desired Depth (the total number of bases sequenced and aligned at a given reference base position). The lower the amount of samples or the higher Gb at higher coverage will raise the cost of sequencing per sample.

Illumina announced in late September that a new sequencing machine will lower the cost to sequence a genome to about \$200 from \$600 using Illumina's older machines. Illumina's new Novseq X series, which incorporates changes to their flow cell (a channel for adsorbing mobile DNA fragments) and minimizing waste from materials, will ship in early 2023. We expect that cost will continue to fluctuate depending on requirements and demand of coverage and depth.

Illumina is facing intensifying competition. China's leading genome sequencing company, BGI Group, is set to enter the U.S. market following a recent legal settlement with Illumina. After years of legal wrangling, an agreement signed this summer between BGI's U.S. subsidiary, MGI and Illumina has given the Chinese firm the green light to sell the CoolMPS sequencer currently and its other models from 2023 onwards. The deal gives BGI the opportunity to challenge Illumina's dominance of the market for sequencers. Additionally, a U.S. court ordered ILMN to pay BGI \$350 million for patent infringement, demonstrating the latter's technological position.

Most sequencing companies, including Illumina, separate the DNA to be deciphered into single strands usually by chopping them into short pieces and mounting on a surface in a flow cell. Each single strand fragment serves as a template to guide the synthesis of a strand with complementary bases, supplied one at a time to channels of beads. Because each added base has been modified to glow, a camera can record where it attaches, and hence the identity of the corresponding base on the original strand. The steps are repeated until the new DNA strand is complete.

Ultima Genomics announced in June that it promises to bring down the cost of WSG to \$100 based on a technology that is more chemistry based. By using an open substrate, Ultima created a massive, low-cost reaction surface that delivers many billions of reads while avoiding costly flow cells and complicated fluidics. Only a fraction of nucleotides are labeled, but the technology uses artificial intelligence to connect the missing pieces. This process allows them to reduce reagent and consumable cost. Ultima's concept is considered a breakthrough, but only if data analysis against known sequencing platforms are confirmed and validated. The company has strategically placed instruments for early access in which data analyses are being reviewed and compared, but it is not in the market for clinical sales. Ultima is preparing to ramp sales along a path similar to Illumina's Novseq X in 2023.

An article in *Science* from June suggests that Ultima's \$100 price only covers reagents. Labor, pre- and post sequencing steps, and initial outlay for the machine which has not been released, are all additional costs to be considered. Even if the \$100 figure is attainable, other companies including BGI also promise a \$100 per human genome.

ProPhase's management reports that it constantly monitors various technologies to determine the best to source for 30x and 100x genome sequencing, which it utilizes for Nebula's *Deep* and *Ultra Deep* products, respectively. 30x generates over 100 gigabytes of DNA data (deep ancestry reports based on Y chromosomal and mitochondrial DNA); 100x decodes 100% of an individual's DNA with ultra high accuracy to generate over 300 gigabytes of DNA data.

ProPhase is technology agnostic. The company is collaborating with and involved in discussions with providers such as Illumina and BGI to ensure that Nebula obtains the most cost-effective pricing to meet the specific requirements, and to ensure that its WSG offering is unparallel to others. The ability to achieve Depth and coverage is only part of the challenge; the other hurdle is that the Gb standard must be met. For example, many companies feel that at 30x, 100Gb is

sufficient to provide the sequence. However, this isn't accurate as genetic mutations may be missed, according to PRPH management. ProPhase is focused on clinical grade sequencing, therefore the company is seeking to bring in 30x and 100x in-house in the very near future. We expect this will be done in partnership with an industry leader.

ProPhase is currently in negotiations with Group 42 (G42), an artificial intelligence and cloud computing company based in Abu Dhabi, United Arab Emirates. G42 is among the global leaders in lowering the cost of whole genome sequencing, though it does not have presence in the United States. Ted Karkus said in PRPH's Q2 2022 earnings call that G42's whole genome sequencing can provide ProPhase with the best pricing. He pointed out that the collaboration with G42 is focused on quality, turnaround time, and scalability. G42 currently holds the most diversified platforms and highest throughput in WGS currently in production, which drives cost benefits and improves turnaround time.

Nebula's workflow includes extractions in-house and collaboration with direct flights to UAE, which reduces logistical time by 50%, according to management. Quality checks are in place in the U.S. and at G42 to ensure sample integrity and stability are consistent. Sequencing that typically takes companies 6 to 8 weeks are also reduced significantly, and the end-to-end process was vetted and tested. Notification of client samples at certain key points in the process are tracked in similar way that Amazon.com updates its customers.

#### Nebula's Business Model

**Clinical genetic testing** is often done through healthcare providers such as physicians and genetic counselors who determine which test is needed, order the test from a laboratory, collect the DNA sample, send the DNA sample to the lab for testing and interpretation, and share the results with the patient. Often, a health insurance company covers part or all of the cost of testing. Direct-to-consumer genetic testing is marketed directly to customers. After purchasing a test kit, customers send the company a DNA sample and receive their results directly from a secure website or app or in a written report. The most popular tests use a limited set of genetic variations to make predictions about a certain aspects of health, provide information about common traits, and offer clues about a person's ancestry.

Nebula sells whole genome sequencing and an initial report at cost, and with it a monthly subscription to genomic research library. The subscription represents all of the profitability at around a 90% margin. In the Q3 2021 earnings call, management had said that Nebula tested between 12,000 and 15,000 customers at the time, though no updated numbers are available. In addition to the proprietary database compiled on these individuals, Nebula has a small team of scientists that curates the library and adds to it every month based on clinical studies published worldwide. The information from studies are integrated with customer genome data and analyzed, in part, using artificial intelligence.

According to Nebula's website, customers are charged for sequencing: \$99 for *Basic* (0.4x), \$299 for *Deep* (30x), and \$999 for *Ultra Deep Whole Genome Sequencing* (100x). Customers are also charged an initial subscription fee (monthly or annual) when their sample has been sequenced and results are ready. If an individual decides to cancel their subscription, they will lose access to their reports and data exploration tools. However, all customers retain access to their genomic data and can download it anytime.

Customers who maintain a subscription receive updates with the latest research in human genomics and how it applies to each individual's genetic makeup. For example, one might learn that she has a predisposition to breast cancer which is much higher the average woman. Nebula provides a polygenic risk score or assessment based on its proprietary database. With genotyping from other companies, results are limited to what variants were decided by that company, which has little value.

A polygenic score based on genetic information is calculated by Nebula for each customer, indicating the collective effect of multiple genetic variants present in their genome. To help interpret polygenic scores, Nebula calculates percentiles that show how a customer's polygenic scores compare to the polygenic scores of other Nebula users. However, because the understanding of human genetics remains limited, having a high or low polygenic score does not necessarily mean a



person is at a significantly greater or lower risk of diseases. Customers are advised to consult their doctor or a specialist to review data in the context of their overall medical history.

Nebula only shares personal information with the explicit permission of customers, who have the choice to participate in Nebula research. The research may be conducted in partnership with third-parties such as non-profit foundations, academic institutions or pharmaceutical companies; or similar third-parties independently performing research with Nebula facilitating access to the data. These studies may focus on a specific group or population, identify potential areas or targets for therapeutics and drug discovery, and genetic research to help in further understanding the relationship between health and the human genome.

Nebula's whole genome sequencing DNA testing kit is the most comprehensive in the consumer market. Sequencing technology decodes 100% of a person's DNA, compared to others that interpret only the most essential parts of DNA. Nebula decodes more than 20,000 genes in the human genome, which can help spot very rare genetic variants that might cause genetic diseases. In addition, it identifies mutations in a customer's genes and allows her to find out more about her oral microbiome, a crucial indicator of disease.

The advantages of Nebula's products are test accuracy, multiple price levels, and rich data and research. Nebula's offerings are more expensive than competitors, whose DNA testing services are less sophisticated and deliver significantly less data and information. With Nebula's higher quality product comes a 12 to 14 week waiting time for results, a required paid subscription (cancelable anytime), and the need for less knowledgeable customers to consult an expert to help decipher personal genome reports. These are factors that may deter some consumers today, however ProPhase anticipates that cost and time will be significantly reduced with its current efforts to improve logistics for whole genome sequencing. And as consumers learn more about genomics, Nebula's reports will be increasingly accessible.

ProPhase is pursuing strategic relationships with major retailers to sell whole genome sequencing kits. Since large retailers will mark-up a product anywhere from 20% to 100%, this indicates that Nebula's product will have to be sold by the company for significantly below the \$299 for its *Deep* product and \$99 for *Basic*. Because price elasticity is a big factor in demand for genome sequencing, management suggests that when Nebula reduces the price to the range between \$30 to \$100, demand will potentially double or triple. We believe that ProPhase is committed to utilizing the lowest cost genome sequencing in the market to guarantee that Nebula will always be the low-cost provider.

Nebula is focusing on the low-throughput (0.4x) product for the retail market. Consumers who purchase at this level will get significantly more genetic information about their genetic makeup than ancestry services such as 23andMe. Beyond this, Nebula expects to up-sell the whole genome sequencing to a portion of those same consumers.

ProPhase has a history of selling dietary supplements and building successful brands such as Cold-EEZE®, with expertise in marketing and distributing to retailers, advertising, fulfillment, and more. Management believes it will obtain a place for Nebula's products in food, drug and mass retail stores. Nebula also has established an online presence, which will grow as its brand is further exposed and WSG prices fall.

For the six months ended June 30, 2022, ProPhase generated approximately \$1.6 million from genomic products and services. The first and second quarters are traditionally the slowest of the year. We note that the biggest selling periods are Black Friday during the Thanksgiving Day holiday and the month of December leading up to Christmas.

While the sale for the subscription to Nebula's proprietary research library is upfront, revenues can only be recognized as the service is provided. For example, if the company sells a three-year subscription to its library, and collects the entire payment upfront from the customer, based on GAAP accounting standards ProPhase must book the revenues over three years even though there is no additional cost after a customer signs up for the library.

## **ProPhase BioPharma**

In June and July 2022, ProPhase introduced a biopharma subsidiary for the licensing, development and commercialization of novel drugs and compounds. The company entered into two license agreements with Global BioLife, Inc. (GBLI), a wholly-owned subsidiary of DSS, Inc. (NYSE-American: DSS) for Equivir and Linebacker.

The initial proprietary compounds licensed by ProPhase BioPharma were developed by Global Research and Discovery Group (GRDG), Global BioLife's scientific research partner. GRDG is a scientific think tank and research organization that works with BARDA (Biomedical Advance Research Development Authority), DARPA (Studies and Defense Advanced Research Projects Agency) and the Potomac Institute for Policy. Its goal is to provide novel, multi-target therapeutics for challenging pharmacological needs to serve military personnel in the battlefield in countries where exposure to diseases such as Ebola and other serious viruses occur, and access to medical treatment is limited.

ProPhase reports that currently planned development costs will be funded out of a small percentage of current working capital or current cash flow. The company has budgeted \$5 million to cover its anticipated expenses related to the research and development for Equivir and Linebacker approximately through year end 2023.

Equivir and Equivir G have shown to be potential treatments to limit the occurrence and or reduce the risk and severity of viral outbreaks. Since 2019, Equivir as a treatment against viral infections has received two U.S. patents and a positive patentability report, increasing the possibility of international patent coverage. The composition is believed to work by potentially blocking the entry of a virus into host cells, which prevents infection and replication in those host cells.

ProPhase said in late June that it will coordinate with Global BioLife to work with Charles River Laboratories, a specialist in preclinical and clinical laboratory services, to complete product testing covering bioavailability, stability, and safety. ProPhase plans to initiate human clinical trials after completion of this product testing. Management points out that the scientist who invented Equivir has a strong relationship with Charles River.

ProPhase intends to introduce Equivir as an OTC supplement to the marketplace in early 2023. Following a strategic roadmap with affinities to Cold-EEZE®, the company will seek to leverage its distribution network in thousands of food, drug and mass-retail stores and online direct to consumer. Equivir is a blend of FDA Generally Recognized as Safe (GRAS) eligible polyphenols, and its composition is projected to come in capsule form and be taken much like a multivitamin. Equivir OTC requires only limited studies to be able to make sufficient claims on the packaging. In relation to this, management will consider shifting Equivir OTC into the TK Supplements division to keep ProPhase BioPharma exclusively focused on drug development.

Equivir G is also a blend of GRAS eligible polyphenols, but with the addition of Gallic acid and still within GRAS rules. ProPhase is in the process of formulating its composition and is preparing clinical studies in accordance with FDA requirements for an Investigational New Drug (IND). ProPhase intends to apply for an IND for Equivir G as a prescription-based antiviral treatment. Potential antiviral applications include SARS-COV2, Influenza and Ebola, among others.

ProPhase BioPharma has exclusive rights worldwide to develop and commercialize Equivir and Equivir G.

Linebacker 1 and 2 (LB-1 and LB-2) are two patented small molecule PIM kinase inhibitors with significant potential across multiple therapeutic indications. They represent a platform of small molecule X-bonded polyphenols. X-bonding is a molecular tuning technique that modifies a natural compound to induce potency, efficacy, bioavailability, and trans-membrane permeability while maintaining safety, toxicity, and tolerability.

Linebacker compounds are modified Myricetin, a common plant-derived flavonoid in the polyphenol group. Myricetin exhibits a wide range of activities that include strong anti-oxidant, as well as potential anticancer, antidiabetic and anti-inflammatory activities by inhibiting TNF- and indication-specific causes. It displays activities that are related to the central



nervous system, and studies have suggested that it may be beneficial to protect against diseases such as Parkinson's and Alzheimer's.

LB-1 is designed as an anti-cancer agent to be used as a co-therapy that targets PIM kinase receptors, a growth factor expressed in cancer. In preclinical laboratory studies, LB-1 inhibited PIM, which could potentially slow the growth of the cancer and allow for better efficacy of the co-therapy drug or treatment being used. Under the terms of the license agreement with GBLI, ProPhase BioPharma has obtained exclusive rights worldwide to develop and commercialize LB-1 and LB-2 for the treatment of cancer, inflammatory diseases or symptoms and memory related syndromes, diseases or symptoms including dementia and Alzheimer's disease.

ProPhase's initial focus for LB-1 is as a potential co-therapy for TAXOL, Doxorubicin, Topotecan, and Cisplatin. Charles River Laboratories has done early studies on Linebacker. Additional preclinical studies of the Linebacker portfolio with each of these four drugs are being conducted by a major U.S. university. We expect new findings to be released in Q4 2022, with further animal studies continuing into 2023.

### **Findings From the Initial LB-1 Cell Line Proliferation in-vitro Studies**

#### *LB-1 Co-Therapy with TAXOL*

LB-1 alone inhibited cell proliferation at 69.94% at 100uM

TAXOL alone inhibited cell proliferation at 41.96% at 200nM

LB-1 and TAXOL combined inhibited cell proliferation at 75.5% (100uM of LB1 + 200nM Taxol)

#### *LB-1 Co-Therapy with Doxorubicin*

LB-1 alone inhibited cell proliferation at 69.66% at 100uM

Doxorubicin alone inhibited cell proliferation at 51.6% at 2000nM

LB-1 and Doxorubicin combined inhibited cell proliferation at 86.95% (100uM of LB1 + 2000nM Doxorubicin)

#### *LB-1 Co-Therapy with Topotecan*

LB-1 alone inhibited cell proliferation at 69.54% at 100uM

Topotecan alone inhibited cell proliferation at 58.27% at 2000nM

LB-1 and Topotecan combined inhibited cell proliferation at 97.18% (100uM of LB1 + 2000nM Topotecan)

#### *LB-1 Co-Therapy with Cisplatin*

LB-1 alone inhibited cell proliferation at 72.33% at 100uM

Cisplatin alone inhibited cell proliferation at 22.74% at 30uM

LB-1 and Cisplatin combined inhibited cell proliferation at 82.48% (100uM of LB1 + 30uM Cisplatin)

Chemotherapy drugs alone, like TAXOL, kill healthy cells alongside tumorous ones. LB-1 is being developed to focus directly on the PIM expressions potentially rendering the cancer cell transcription and replication useless, so chemotherapy drugs such as TAXOL can effectively kill the existing tumor cell. LB-1 may also be developed as a potential standalone post therapy to ensure cancer cells do not regenerate. TAXOL is among the most affordable and best-selling chemotherapy drugs, with annual sales over \$1 billion.

Under the agreement for Linebacker, ProPhase BioPharma paid Global BioLife a one-time upfront license fee of \$50,000 and must pay an additional \$900,000 following the achievement of a first Phase 3 study, with an additional \$1 million upon regulatory approval of a New Drug Application (NDA) for the first licensed product. ProPhase BioPharma is also required to pay to GBLI 3% royalties on net revenue of each licensed product, but no less than the minimum royalty of \$250,000 of net revenue per year minus royalty payments for any required third-party licenses.



As part of the agreement, ProPhase BioPharma also formed an advisory board with Daryl Thompson as its founding member. Thompson is President and Director of Scientific Initiatives at GRDG and is a biochemist twice nominated for the Nobel Prize in 2015 and 2016 for his work in cutting-edge organic and carbohydrate chemistry. ProPhase plans to work with Daryl Thompson and GRDG to continue the development of the Linebacker portfolio, as well as on other important compounds in the future.

## **TK Supplements**

ProPhase develops and markets OTC health products through TK Supplements (TKS). Its product line promotes better health, energy and sexual vitality. TKS's herbal supplements are characterized by the company as an optimum blend of ingredients to ensure premium quality products. Formulations are derived from natural ingredients and enhanced by science. The TK Supplements® product line includes Legendz XL®, a male sexual enhancement and Triple Edge XL®, an energy and stamina booster.

In Fiscal 2020, TKS extended distribution of Legendz XL® to include more customer accounts including national chain drug retailers, internet-based retailers and several regional retailers and leveraged its existing infrastructure and retail distribution platform. Legendz XL® currently has distribution in Rite Aid, Walgreens and other retailers, and via ecommerce, and is now achieving broader distribution at CVS and Walmart. ProPhase also has produced a television commercial and initiated television and digital media testing for Legendz XL® for marketing to consumers. The company completed a broad series of clinical studies that support important product claims that it has incorporated into product packaging and marketing communications for Legendz XL®.

TKS also introduced Triple Edge XL® to a limited number of retail customers in Fiscal 2020 and has gained distribution with one large national chain drug retailer. Management anticipates growth from the TK Supplements® product line as the company optimizes its market strategy and expands channels of distribution. However, there can be no assurance that these efforts will result in any revenue growth.

## **Pharmaloz Manufacturing**

Pharmaloz Manufacturing is a full-service contract manufacturer and private label developer of a broad range of non-GMO, organic and natural-based cough drops and lozenges and OTC drug and dietary supplement products. PMI provides consumer product development, pre-commercialization services, production, warehousing and distribution services for its customers. Its 60,000 square-foot manufacturing facility, located in Lebanon, Pennsylvania, is registered with the FDA and is certified organic and kosher.

Pharmaloz partners with brokers and retailers for private label products, offers the ability deploy various strategies to help customers market their products, and works to develop and formulate customers' unique products. As part of the \$50 million sale of ProPhase's former Cold-EEZE® business to Mylan Inc. in March 2017, the two companies entered into a manufacturing agreement for Pharmaloz to supply various Cold-EEZE® lozenge products to Mylan and now Vespyr Brands, which subsequently acquired Cold-EEZE® from Mylan.

Sales for ProPhase's lozenges manufacturing business jumped during the surge in COVID-19. When the pandemic had temporarily subsided in 2021, ProPhase spent the next few quarters burning through inventory. The outlook for the second half of 2022, however, is once again strong based on a better inventory situation and new customer initiatives.

FINANCIAL PERSPECTIVE

ProPhase Labs' financial outlook has improved over the last two years, catapulted by soaring demand for COVID-19 testing at its high-efficiency diagnostics laboratory. PRPH's financials reflect a pattern of minimally dilutive financings, strong revenue, earnings and margin growth, and a markedly improved balance sheet. Virtually all gains over the last 12 months are attributed to organic growth. We refrain from earnings estimates and other financial projections due to the complete uncertainty of assumptions in the analysis of development-stage technology and life science companies.

**ProPhase Labs, Inc. – Financial Highlights: Fiscal Year 2017 to Present**

Fiscal Years (Dec. 31)	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	LTM (Q2-22)
(In millions)						
Total Revenues	9.9	13.1	9.9	14.5	79.0	131.3
Total Revenues (CAGR 1Y %)	134	33	(25)	47	444	292
Gross Profit	1.9	4.8	2.6	4.6	42	76
Gross Profit Margin %	19.7	36.4	26.5	31.7	53.1	57.9
EBITDA	(3.7)	(1.3)	(2.8)	(3.5)	13.0	41.4
EBITDA Margin %	-	-	-	-	16.5	31.5
Net Income	41.8*	(1.6)	(3.1)	(2.3)	6.3	26.6
Net Income Margin %	-	-	-	-	7.9	20.2
Diluted EPS (\$)	2.69	(0.14)	(0.27)	(0.20)	0.40	1.37
<b>Capital Structure</b>						
Diluted Shares Outstanding	15,696	11,396	11,564	11,595	18,393	17,234
Total Cash and Short Term Invest.	21.9	8.2	1.4	8.5	17.3	27.5
Total Debt	-	-	-	14.7	14.9	12.7
Enterprise Value (EV)	10.1	27.2	21.2	118.3	106.8	184.7
<b>Cash Flow Analysis</b>						
Cash from Operations	(2.8)	(2.1)	(0.8)	(2.6)	(13.6)	14.9
Capital Expenditure	(0.2)	(0.1)	(0.2)	(1.7)	(4.2)	(1.8)

Source: Koyfin, FactSet

\*As a consequence of the sale of the Cold-EEZE® business to Mylan in March 2017, ProPhase realized a gain, net of income tax, of \$27.0 million for the year ended December 31, 2017. The gain on the sale of the Cold-EEZE® Business is classified as a component of discontinued operations at December 31, 2017 and is net of approximately \$18.8 million for estimated income taxes arising from the sale. For the year ended December 31, 2017, the company also realized an income tax benefit from continuing operations of \$18.0 million as a consequence of the utilization of the federal and state net operating losses.

ProPhase currently disaggregates revenue from contracts with customers into four categories: diagnostic services, contract manufacturing, retail and others, and genomic products and services. The company believes this most accurately depicts how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic factors. ProPhase's revenue by source for the three and six months ended June 30, 2022 and 2021 (in thousands) follows:

Revenue by Customer Type	For the three months ended		For the six months ended	
	June 30, 2022	June 30, 2021	June 30, 2022	June 30, 2021
Diagnostic services	\$ 26,158	\$ 7,536	\$ 71,071	\$ 20,274
Contract manufacturing	1,759	1,041	2,913	2,949
Retail and others	465	565	1,011	1,190
Genomic products and services	710	-	1,628	-
Total revenue, net	\$ 29,092	\$ 9,142	\$ 76,623	\$ 24,413

Diagnostic services accounted for 92.7% of total revenue for the first six months of 2022. Contract manufacturing and retail/others totaled 5.1%, and genomic products and services represented 2.1%. This marks a huge shift from the



revenue distribution in fiscal 2020, when diagnostic services contributed only 8.8% or \$1.27 million, in comparison to the 91.2% or \$13.2 million generated by OTC consumer healthcare products and dietary supplements.

### **Seasonal Factors**

The company's consumer sales are influenced by several factors, including the timing of acceptance of TK Supplements® consumer products in the marketplace, and fluctuations in the timing of purchase and the ultimate level of demand for the OTC healthcare and cold remedy products that ProPhase manufactures, which is largely a function of the timing, length, and severity of each cold season.

The majority of products ProPhase manufactures for its customers are OTC healthcare and cold remedy products. As a consequence, revenues tend to be higher in the first and fourth quarters during the cold season. In general, a cold season is defined as the period from September to March when the incidence of the common cold rises due to the change in weather and other factors. The third quarter has been the weakest quarter for ProPhase throughout its history. Management reports that the same seasonality occurs with COVID testing because of the low incidences of flu and colds in the summertime. This dramatically reduces the confusion over whether a person has COVID or another infection.

Nebula Genomics' testing business is in the early stage and therefore has limited experience in the marketplace. However, we believe that seasonality will similarly affect demand for personal genomics test kits. Genetic-testing company 23andMe reports in SEC filings that its Personal Genome Service (PGS) business historically has been seasonal. It generates a significant amount of PGS revenue during the first quarter of the calendar year due to seasonal holiday demand and its higher advertising expenditures during the holiday period. We expect that a similar pattern will occur as demand for Nebula's personal genomics products and services increase.

### **History of Special Dividends and Stock Buybacks**

ProPhase distributes special dividends on occasion. The company returned a total \$2.40 per share to its stockholders between June 2018 and June 2022. In addition, the company has repurchased PRPH shares exceeding \$2 million in value since 2021. ProPhase currently has a \$6 million share buyback plan yet to be utilized.

### **Financings and Capital Availability**

In September 2020, ProPhase issued two unsecured, partially convertible, promissory notes for an aggregate principal amount of \$10 million to two investors. The proceeds from these notes were used for working capital and general corporate purposes, which included capital expenditures and acquisitions.

In January 2021, ProPhase completed two separate equity offerings involving a total of 3,550,000 shares of common stock for net proceeds of \$40.6 million. Notably, PRPH completed a public offering of three million shares of common stock at a price to the public of \$12.50, more than 800% higher than the share price six months earlier. The net proceeds derived from these equity offerings were used principally for expansion of the diagnostics services business.

At-the-Market (ATM): On December 28, 2021, ProPhase entered into a sales agreement with ThinkEquity LLC, under which ProPhase may offer and sell, from time to time through the sales agent, shares of common stock having an aggregate offering price of up to \$100,000,000, subject to certain terms in the agreement. ProPhase is not obligated to make any sales of shares under the sales agreement. As of June 30, 2022, PRPH has sold no shares under the ATM agreement.

RISK FACTORS

Numerous risks exist for any development stage company in the life science industry. ProPhase is not immune to potential setbacks, despite vastly improved fundamentals over the last two years. We highlight several factors that deserve recognition:

- CEO and Chairman Ted Karkus owns 19.4% of ProPhase common stock. He exerts significant influence over the outcome of all matters submitted to stockholders for approval, including the election of directors. Consequently, he exercises substantial influence over major decisions including those which could result in or prevent a change of control of the company. Also, circumstances may occur in which the CEO's interests could be in conflict with the interests of other stockholders, thus limiting a stockholder's ability to influence the company through voting their shares.
- The diagnostic service business is subject to extensive federal, state, and local laws and regulations, all of which are subject to change, as well as laws and regulations governing the submission of claims for payment for ProPhase services, such as those relating to: coverage of services under Medicare, Medicaid and other federal health care programs; the amounts that the company may bill for its services; and the party to which it must submit claims. Also, reimbursement policies and requirements for some payers and procedures are ambiguous, which could lead to billing errors and related disputes. There can be no assurance that ProPhase's efforts to offer and perform COVID-19 or other diagnostic testing will be successful in the future or that the revenue and operating profits from such business will increase or maintain their current level.
- ProPhase's customer base for its COVID-19 tests is principally comprised of governmental bodies, municipalities, and large corporations who pay the company directly or through third-party payors. In March 2020, the \$2.2 trillion Coronavirus Aid, Relief, and Economic Security Act passed in response to the economic fallout of the COVID disease. The 'CARES Act' enabled reimbursement to healthcare providers for COVID-19 tests provided to uninsured individuals, subject to continued available funding. Approximately 48% and 79% of ProPhase Diagnostics services revenue for the six months ended June 30, 2022 and 2021, respectively was generated from this program for the uninsured.
- The Affordable Care Act brought significant changes to the way healthcare is financed by both the government and private insurers, and significantly impacted the U.S. pharmaceutical industry, including expanding the list of covered entities eligible to participate in the 340B drug pricing program and establishing a new Medicare Part D coverage gap discount program. In the future, these and other healthcare reform measures may result in more rigorous coverage criteria and lower reimbursement, and in addition, exert downward pressure on pricing for any of ProPhase's approved products. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may hinder ProPhase in generating revenue, attaining profitability, or commercializing products once, and if, marketing approval is obtained.
- Collections of ProPhase Diagnostics services revenues are driven by payers, which are government agencies (primarily HRSA), insurance providers, and client payers. In Fiscal 2021, requisitions from each payer group were 60%, 35%, and 5%, respectively.
- Diagnostic services revenues are subject to fluctuations in COVID-19 testing demand. The demand for COVID-19 tests has been, and ProPhase expects it to continue to be, highly volatile, primarily driven by the emergence and severity of new variants, which are unpredictable.
- Total net revenue for Fiscal 2021 was \$79.0 million. Three clients of ProPhase Diagnostics accounted for 23.5%, 17.9%, and 11.9%, respectively, of the company's revenue for the year ended December 31, 2021.

- IT systems are used extensively in virtually all aspects of ProPhase's business, including clinical testing, test reporting, billing, customer service, logistics and management of medical data. The company's success depends, in part, on the continued and uninterrupted performance of its IT systems. A failure or delay in the IT systems could impede ProPhase's ability to serve its customers and patients and protect their confidential data.
- ProPhase is involved in the early development of biopharma compounds and drugs. Clinical trials are expensive, time consuming, and subject to uncertainty. There is no guarantee that any of the company's clinical trials will be conducted as planned or completed on schedule, if at all. Issues may arise that could suspend or terminate clinical trials. A failure of one or more of the company's clinical trials may occur at any stage of testing. Clinical trials may fail to adequately demonstrate the safety and efficacy of product candidates and the development of product candidates may be delayed or unsuccessful, which could prevent or delay regulatory approval and commercialization.
- The company's consumer sales are and will continue to be influenced by (i) the timing of acceptance of TK Supplements® consumer products in the marketplace, and (ii) fluctuations in the timing of purchase and the ultimate level of demand for the OTC healthcare and cold remedy products that ProPhase manufactures, which is largely a function of the timing, length and severity of each cold season.

*Antivirals* – a class of medication used for treating viral infections. Most antivirals target specific viruses, while a broad-spectrum antiviral is effective against a wide range of viruses. Unlike most antibiotics, antiviral drugs do not destroy their target pathogen; instead, they inhibit its development.

*Clinical Laboratory Improvement Act (CLIA)* – regulates the operations of virtually all clinical laboratories, requiring that they be certified by the federal government and that they comply with various technical, operational, personnel and quality requirements intended to ensure that the services provided are accurate, reliable and timely.

*Deoxyribonucleic Acid (DNA)* – a molecule that encodes an organism's genetic blueprint. DNA is a linear molecule composed of four types of smaller chemical molecules called nucleotide bases: adenine (A), cytosine (C), guanine (G), and thymine (T). The order of these bases is called the DNA sequence. Segments of DNA that carry genetic information are called genes, and they are inherited by offspring from their parents during reproduction.

*Diagnostic Test Validation* – a process that determines the fitness of an assay that has been properly developed, optimized and standardized for an intended purpose(s). Validation includes estimates of the analytical and diagnostic performance characteristics of a test.

*Gallic Acid* – a phenolic acid widely distributed in many different families of higher plants, both in free state, and as a part of more complex molecules.

*Genome* – all genetic information of an organism. The human genome consists of more than six billion of those nucleotide base pairs arranged in specific sequences that code for between 20,000 and 25,000 different genes. Most of those genes are the same in every human, but less than 1% of those genes are just slightly different, making every person unique.

*Genome Sequencing* – a comprehensive method for analyzing entire genomes. Genomic information has been instrumental in identifying inherited disorders, characterizing the mutations that drive cancer progression, and tracking disease outbreaks. Rapidly dropping sequencing costs and the ability to produce large volumes of data with today's sequencers make whole-genome sequencing a powerful tool for genomics research.

*Genomics* – the study of the genome. The International Human Genome Project reported the sequence of the genome for *Homo sapiens* in 2004, although the initial 'finished' sequence was missing 8% of the genome consisting mostly of repetitive sequences. With advancements in technology that could handle sequencing of the many repetitive sequences found in human DNA that were not fully uncovered by the original Human Genome Project study, scientists reported the first end-to-end human genome sequence in March 2022.

*Genotype* – a scoring of the type of variant present at a given location in the genome. It can be represented by symbols. For example, BB, Bb, bb could be used to represent a given variant in a gene. Genotypes can also be represented by the actual DNA sequence at a specific location, such as CC, CT, TT. DNA sequencing and other methods can be used to determine the genotypes at millions of locations in a genome in a single experiment. Some genotypes contribute to an individual's observable traits, called the phenotype.

*Generally Recognized as Safe (GRAS)* – an FDA designation that a chemical or substance added to food is considered safe by experts under the conditions of its intended use. An ingredient with a GRAS designation is exempted from the usual Federal Food, Drug, and Cosmetic Act food additive tolerance requirements.

*Investigational New Drug Application (IND)* - a request from a clinical study sponsor to obtain authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans.

Myricetin – a hexahydroxyflavone that is flavone substituted by hydroxy groups at positions 3, 3', 4', 5, 5' and 7. It has been isolated from the leaves of *Myrica rubra* and other plants. It has a role as a cyclooxygenase 1 inhibitor, an antineoplastic agent, an antioxidant, a plant metabolite, a food component, a hypoglycemic agent and a geroprotector. It is a hexahydroxyflavone and a 7-hydroxyflavonol. It is a conjugate acid of a myricetin(1-).

Over-the-Counter (OTC) Supplements – dietary supplements or dietary ingredients include vitamins, minerals, herbs, amino acids, and enzymes. Under the Dietary Supplement Health and Education Act of 1994, the FDA is responsible for ensuring that manufacturers and distributors meet the current requirements. These entities are not allowed to advertise their products in an adulterated way, and they are responsible for evaluating the safety and labeling of their product.

Personal Genomics – also known as consumer genetics, is the branch of genomics concerned with the sequencing, analysis and interpretation of the genome of an individual. The genotyping stage employs different techniques, including single-nucleotide polymorphism analysis chips (typically 0.02% of the genome), or partial or full genome sequencing. Once the genotypes are known, the individual's variations can be compared with the published literature to determine likelihood of trait expression, ancestry inference and disease risk.

PIM Kinase Inhibitor – a class of medical drugs that are mainly used to treat advanced cancers. They function by inhibiting one or more of the phosphoinositide 3-kinase (PI3K) enzymes, which are part of the PI3K/AKT/mTOR pathway. This signal pathway regulates cellular functions such as growth and survival. It is strictly regulated in healthy cells, but is always active in many cancer cells, allowing the cancer cells to better survive and multiply. PI3K inhibitors block the PI3K/AKT/mTOR pathway and thus slow down cancer growth. They are examples of a targeted therapy.

Polymerase Chain Reaction (PCR) – a test to detect genetic material from a specific organism, such as a virus. The test detects the presence of a virus if you have the virus at the time of the test. The test could also detect fragments of the virus even after you are no longer infected.

Polyphenols – a large family of naturally occurring organic compounds characterized by multiples of phenol units. They are abundant in plants and structurally diverse.

Precision Medicine – an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person. This approach will allow doctors and researchers to predict more accurately which treatment and prevention strategies for a particular disease will work in which groups of people. It is in contrast to a one-size-fits-all approach, in which disease treatment and prevention strategies are developed for the average person, with less consideration for the differences between individuals.

TNF Inhibitors – drugs that help stop inflammation and are used worldwide to treat inflammatory conditions such as rheumatoid arthritis, psoriatic arthritis, juvenile idiopathic arthritis, inflammatory bowel disease (Crohn's and ulcerative colitis), ankylosing spondylitis, and psoriasis.

Whole Genome Sequencing (WGS) – the process of determining the entirety, or nearly the entirety, of the DNA sequence of an organism's genome at a single time. This entails sequencing all of an organism's chromosomal DNA as well as DNA contained in the mitochondria. WGS has largely been used as a research tool, but was being introduced to clinics in 2014. In the future of personalized medicine, whole genome sequence data may be an important tool to guide therapeutic intervention.





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Third Stream Research (TSR) covers the new generation of emerging growth companies that are successfully leveraging digital transformation. We focus on the powerful trends impacting revenue growth and margin expansion, capital allocation, and corporate valuation. Our investment perspectives serve Wall Street's buy-side and sell-side.

Joshua Levine, principal at Third Stream Research, has more than 30 years of experience in the financial markets, most recently as Senior Research Analyst for 451 Research, a division of S&P Global Market Intelligence, where he covered the intersection of macroeconomic and IT industry trends.

Synthesizing top-down and bottom-up analysis into a third stream, TSR connects patterns of innovation, macroeconomic structures and behavior, and qualitative research to identify decisive factors influencing valuation. This approach was the basis for the creation of Third Stream Research.

Apart from independent research, TSR provides sponsored research and advisory services to help companies build recognition of intrinsic value in the Wall Street community, strengthen the foundation of shareholders, raise trading volume/liquidity, and lower the cost of capital.

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