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Brad Sorensen
312-265-9674
bsorensen@zacks.com

scr.zacks.com

101 N. Wacker Drive, Chicago, IL 60606

Yd Biopharma (YDES-NASDAQ)

YD Biopharma is an integrated biotechnology company that is poised to have a transformational year as it expands business operations.

Research Note

YD Bio (YDES) is an integrated biotechnology company that combines diagnostics, precision medicine and regenerative ophthalmology under a single commercial and development strategy. The company's mission centers on early cancer detection using blood-based diagnostic tests, development of exosome-based therapeutics and tools for ophthalmic conditions, and infrastructure to support translational clinical work and manufacturing. Over the past year, the company has positioned itself for 2026 to be a year of catalysts for the company, meaning we suggest investors look at YD Bio now, before those catalysts begin to take full effect. YD Bio has grown from a research-focused origin into a public company aiming to commercialize both platform diagnostics and product candidates while supporting services that feed its R&D engine. YD Bio is transforming from a platform validation company to one focused on clinical and commercial development.

Recent Developments

Before getting into the detail, two recent announcements illustrate how YD management is already pushing those catalysts forward. The company announced that Comprehensive Chemistry, Manufacturing, and Controls (CMC) development has been achieved for the Limbal Stem Cell (LSC) platform and LSC-derived exosome products. This achievement allows the company to plan on advancing two lead ophthalmology programs using that platform. These programs include Dry Eye Disease, which the company is developing drops for and expects initiation of a Phase I trial in 2027, and Age-Related Macular Degeneration, which the company projects to have first-in-human trials on in 2027.

The second announcement features an example of a strategic move by the company that sets them up for more efficient growth in the future. The company announced it has entered into a Memorandum of Understanding to merge with EG BioMed, which is a biotechnology company specializing in DNA methylation–based cancer diagnostics and AI-driven biomarker analytics. Although this memorandum is non-binding and could fall apart, we believe it shows the foresight of management in attempting to build an integrated, data-driven oncology platform spanning early cancer detection, real-world clinical data generation, and AI-enabled drug discovery.

The Company

Getting back to the overall view of the company, YD Bio activities span biomarker discovery, testing development, clinical validation and regulatory engagement. Its diagnostics work emphasizes DNA methylation and cell-free DNA approaches for early cancer detection and post-treatment surveillance; the company has supported or partnered on tests that monitor methylation markers and is working to move toward broader clinical use. Alongside diagnostics, the organization is developing exosome and stem-cell

derived therapeutics targeted at ophthalmology —including contact-lens based exosome delivery and topical exosome/artificial-tear formats aimed at dry eye and other ocular surface conditions. To support U.S. regulatory interactions and clinical programs, YD Bio has recently announced plans for a California operations center and capital/operational investment to ramp up GMP and clinical-trial enabling capabilities.

The company's commercial and partnership model blends in-house product development with strategic collaborations and service lines. YD Bio has said it will pursue both direct commercialization in select markets and work with clinical laboratory and industry partners to deploy assays under laboratory authorizations or through sublicenses; a recent example is cooperation to broaden access to an OkaiDx cfDNA methylation test for post-treatment breast cancer monitoring, where YD Bio's role is supporting commercialization alongside a CLIA/CAP lab partner. In parallel, YD Bio operates or is affiliated with technology and service units that provide nucleic-acid and reagent solutions, which can create near-term revenue streams and vertical integration between reagent/service sales and the company's internal diagnostic development.

Following its recent Nasdaq listing, YD Bio has access to public-market capital that management plans to use judiciously to help fund clinical development, manufacturing scale-up, and U.S. market expansion. Company management has emphasized a pathway that prioritizes clinical validation of lead diagnostics, staged regulatory engagement (including FDA interactions supported by the planned California center), build-out of GMP-capable facilities or partnerships for product supply, and moving ophthalmic exosome candidates into first-in-human testing or regulatory filings where appropriate.

To dive into the operations of the company a bit more, DNA methylation, which is a key component of the company's cancer screening operations, is a fundamental biological process that cells use to regulate how genes are turned on and off without changing the underlying DNA sequence itself. According to company management, the company's DNA-methylation-based diagnostics is being adopted by leading medical centers and is expected to help grow revenues in a rapid way.

DNA methylation belongs to a broader category known as epigenetics, which refers to chemical modifications that influence gene activity and cellular behavior while leaving the genetic code intact. In DNA methylation, a small chemical group called a methyl group is added to specific positions on the DNA molecule, most commonly at cytosine bases that sit next to guanine bases in regions known as CpG sites. This simple chemical tag can have a powerful effect on whether a gene is actively expressed or effectively silenced.

In normal, healthy cells, DNA methylation follows tightly controlled patterns that help guide development and maintain normal cell function. These patterns ensure that genes needed for a particular cell type are active, while genes that are unnecessary or potentially harmful remain switched off. Methylation also plays an important role in stabilizing the genome by suppressing repetitive DNA elements and maintaining chromosomal integrity. Because these patterns are faithfully copied when cells divide, DNA methylation helps preserve cellular identity over time.

When methylation patterns become disrupted, the consequences can be profound. Abnormal methylation is a hallmark of many diseases, particularly cancer. Tumor cells often show widespread loss of methylation across large regions of the genome, combined with excessive methylation at specific gene promoters, especially those that normally act as tumor suppressors. This imbalance can silence genes that protect against uncontrolled growth while allowing cancer-promoting pathways to remain active. Importantly, these aberrant methylation changes often occur very early in disease development, sometimes before symptoms or structural changes can be detected.

Because DNA methylation changes are stable, frequent, and disease-specific, they have become especially valuable as biomarkers, when harnessed and perfected such as the work YD has done. Methylation patterns can be detected not only in tissue samples but also in small fragments of DNA circulating in the blood, known as cell-free DNA. This makes methylation-based testing well suited for

noninvasive diagnostics, early cancer detection, monitoring of residual disease after treatment, and tracking recurrence, which is what makes this YD system so valuable and why its diagnostic system is being rapidly adopted.

In concert with the DNA methylation, YD Bio's laboratory testing services center on making advanced molecular diagnostic tests available through accredited clinical laboratories and on providing specialized nucleic acid technology services under its YD BioLabs banner, further contributing to revenue sources for the company.

At the clinical services level, YD Bio supports the OkaiD testing platform, which uses circulating cell-free DNA (cfDNA) methylation patterns as a basis for detecting and monitoring cancer. This platform has been made accessible in the United States through YD Bio's partner, EG BioMed's CLIA/CAP-certified laboratory in Washington state. That accreditation is significant because it means the lab meets high standards for quality and consistency in testing operations, enabling it to run what are known as laboratory-developed tests (LDTs). Through this arrangement, blood-based OkaiDx tests are now offered for surveillance of post-treatment breast cancer and expanded to include tests aimed at pancreatic and colorectal cancer detection across many U.S. states, supported by virtual physician networks and at-home blood collection for patient convenience. These services rely on cfDNA methylation profiling to generate clinically relevant information that can aid in early detection and disease monitoring. These services are so valuable to YD that management announced a potential merger of the two companies (mentioned above) that enables YD BioMed to accelerate its transition from a technology-focused company into a platform-based biotech organization anchored in clinically validated molecular data, a move that we believe will pay great dividends going forward. By putting the diagnostic arm of the company under one umbrella, which includes diagnostics, clinical data, and AI intelligence, the company aims to accelerate time-to-market, and build a scalable oncology innovation ecosystem addressing cancer from early detection through treatment monitoring and recurrence prevention.

In addition to these clinical molecular diagnostics, YD Bio operates lab-oriented service lines that cater to other organizations' needs in nucleic acid technology and enzyme engineering. Through YD BioLabs, the company provides end-to-end solutions for commercial and research customers working with DNA and RNA tools, offering custom oligonucleotide modification, scalable site-specific labeling of probes and barcodes, and antibody-oligonucleotide conjugation (AOC) capabilities. These services support innovators who require and are willing to pay for tailor-made nucleic acid reagents for next-generation diagnostics, research assays or therapeutic platforms. YD BioLabs also functions as a specialist enzyme CDMO, designing, engineering and purifying bespoke nucleic acid enzymes optimized for specific applications such as amplification, labeling or sequencing workflows, with quality validation to ensure activity and stability, all of which we believe will be increasingly in demand.

Moving to YD Bio's exciting work around eye-related products, which involves both near-term commercial ophthalmic offerings and a longer-term regenerative therapeutic pipeline focused on unmet needs in eye health. Management believes this is a core strategic pillar for the company alongside its diagnostics business discussed above, and has started moving products from concept to real-world availability.
To begin with the commercial side, YD Bio has secured clearances and compliances that allow it to sell eye-care products in the United States. Through its partnership with 3D Global Biotech, the company's Exovisse Contact Lenses received FDA 510(k) clearance as a Class II medical device, meaning regulators have determined these lenses are substantially equivalent to legally marketed devices and can be marketed in the U.S. This gives YD Bio a foothold in the large contact lens market and a revenue stream that is not dependent on potential drug approvals. Additionally, the company's Exovisse Artificial Tears were developed in compliance with the FDA OTC Final Monograph M018, permitting nationwide over-the-counter distribution without individualized premarket approval, so these lubricating drops for dryness and eye comfort can be sold widely in pharmacies and retail settings.

In addition to those products already cleared for sale, YD Bio's broader ophthalmic portfolio includes specialized contact lenses that emphasize comfort and hydration, designed with advanced materials and surface technologies that aim to reduce dryness and irritation during wear, and supportive solutions like

the 3D LensMate system meant to enhance hydration and fit. These products illustrate how the company is applying engineering and material science to everyday eye care needs and continually looking to expand its portfolio.

Beyond consumer-oriented products, YD Bio's pipeline encompasses regenerative therapeutic development centered on limbal stem cells (LSCs) and exosome technology. Exosomes are tiny vesicles secreted by cells that carry signaling molecules, and YD Bio is investigating how exosomes derived from limbal stem cells might support healing and regenerative processes on the ocular surface and potentially deeper eye tissues. The company has enrolled its limbal stem cells and LSC-derived exosomes in the FDA Drug Master File, a regulatory step that documents quality and manufacturing information and can support future therapeutic filings. This isn't itself an approval to market a drug, but it lays groundwork for studying exosome-based therapies in clinical trials and, eventually, seeking formal approvals. Company management also just announced that YD Bio has achieved comprehensive Chemistry, Manufacturing, and Controls (CMC) development for its LSC platform and LSC-derived exosome products. This includes successful batch testing and qualification of primary LSC cell sources, establishment of scalable cell expansion and cryopreservation methods, and definition of cell specifications. Furthermore, robust exosome expansion, purification, and potency testing methods have been developed, alongside established exosome specifications. Relevant supporting Standard Operating Procedures (SOPs) are finalized, ensuring manufacturing readiness for Investigational New Drug (IND) applications, all of which aids in the acceleration toward commercialization.

As part of those longer-term development efforts, YD Bio and 3D Global Biotech are planning a clinical trial in Taiwan to evaluate treatments for dry eye disease, which remains a condition with high prevalence and unmet treatment needs. Beyond dry eye, they are pursuing exosome applications in formats such as injections and eye drops aimed at retinal and macular disorders, signaling a broader vision toward therapies that could influence deeper, more complex ocular conditions if clinical evidence supports safety and effectiveness.

Add this impressive portfolio of eye care products and developing treatments, with extensive revenue opportunities, to the above described DNA methylation work for early cancer diagnosis and you have a company that has great potential, with various income stream opportunities, that we believe investors with a higher risk tolerance should consider adding YDES to their portfolio.

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