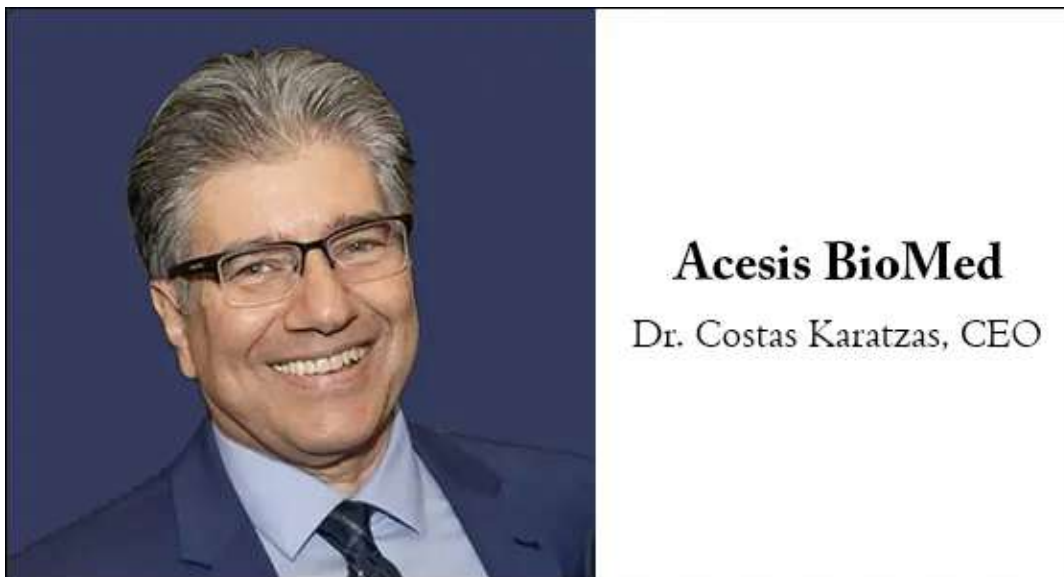


4.0 -53.50 (-0.23%) | EUR to USD 1.16590 -0.00 (-0.37%) | Bitcoin 116,057 -1,433 (-1.22%)

## Smartest Companies to Watch 2025

# Acesis BioMed: Introducing Innovative Treatment for Restoring Testosterone Deficiency

Business Honor



***"With a strong scientific foundation, a clear market opportunity, and visionary leadership, Acesis BioMed is poised to redefine the standard of care for male hypogonadism and related conditions."***

The need for innovative and safer treatments for male hypogonadism, also referred to as low testosterone, is greater than ever in the quickly changing healthcare environment of today. Although they are useful in raising hormone levels, traditional testosterone replacement treatments (TRTs) frequently have a number of possible drawbacks and restrictions.

Here comes—Acesis BioMed, a biomedical business committed to using non-steroidal, oral peptide therapies to transform the treatment of low testosterone. Acesis BioMed aims to develop a novel and effective alternative to traditional treatments by focusing on restoring the body's natural testosterone



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Testosterone deficiency affects a significant portion of the male population, with prevalence rates ranging from 10% to 40%. This condition not only impacts sexual health but also contributes to fatigue, depression, reduced muscle mass, and an increased risk of metabolic disorders, starting at approximately the age of 30, men's testosterone levels naturally decline by 0.4 to 2% per year.

Traditional TRTs, which involve the administration of synthetic testosterone, have been associated with adverse effects such as infertility and potentially cardiovascular complications and prostate issues.

Following the TRAVERSE trial, the FDA issued updated labeling guidance on February 28. While the "*Limitation of Use*" label for age-associated hypogonadism remains, the requirement for a Boxed Warning regarding the risk of cardiovascular events has been removed and a new warning has been added stating the potential increase in blood pressure.

## Acesis BioMed: Company Overview

Founded with the mission to transform the treatments for male hypogonadism, Acesis BioMed operates through its subsidiaries—Acesis Biomed US, Inc. in Colorado, USA, and Acesis Biomed Ltd in London, UK. The company's primary focus is the development of a platform of oral drug candidates targeting metabolic and endocrine disorders, with an initial emphasis on male hypogonadism. By utilizing advanced research and a deep understanding of steroidogenesis based on the expertise of its co-founder Dr. Papadopoulos, Acesis BioMed aims to develop novel treatments.

## Innovative Therapeutic Approach

Acesis BioMed's innovation is their patented drug candidate pipeline ACE-167. Unlike traditional TRTs that require administration of exogenous testosterone, the ACE-167 pipeline is a non-steroidal treatment comprised of short peptides designed to stimulate the body's own testosterone production – the Leydig cells of the testes. This approach aims to mitigate the risks associated with synthetic hormone administration, such as cardiovascular issues and infertility. Moreover, ACE-167 is formulated for oral administration, enhancing patient compliance compared to injectable or transdermal therapies.

## Scientific Foundation

The development of ACE-167 is rooted in the research of Dr. Vassilios Papadopoulos, a globally recognized expert in steroidogenesis. Dr. Papadopoulos and his team identified the 14-3-3 $\epsilon$  protein as a critical negative regulator of steroid hormone biosynthesis. By developing peptide-based compounds that modulate this inhibitory process, Acesis BioMed aims to restore natural testosterone production. Extensive research has demonstrated that these peptides can effectively disrupt the



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## Market Opportunity

As of 2024, the global testosterone replacement therapy market was approximately \$2.04 billion, projected to expand to \$2.53 billion by 2029, growing at a rate of 4.32% per year. Continuing this uptrend, the market is expected to reach approximately \$3.06 billion by 2034, with a CAGR of 3.88%. Factors driving this growth include an aging male population, increased awareness of testosterone deficiency, and the limitations of existing therapies. Acesis BioMed's unique approach positions the company to capture a significant share of this expanding market by offering treatment that addresses the unmet needs of safety and efficacy in hypogonadal men and co-morbidities. For example, it is estimated that ~30–50% of men with obesity or diabetes Type 2 have low testosterone.

As the understanding of testosterone deficiency and its broader health implications continues to evolve, the need for safer and more effective treatments becomes increasingly apparent. Acesis BioMed stands at the forefront of this transformation, offering innovative solutions that harness the body's natural processes to restore hormonal balance. With a strong scientific foundation, a clear market opportunity, and visionary leadership, Acesis BioMed aims to develop a novel and effective alternative to traditional treatments by focusing on restoring the body's natural testosterone production processes.

## Acesis BioMed's Advanced Peptide-Based Approach

Testosterone deficiency arises from various factors, including primary and secondary hypogonadism, acquired hypogonadism due to circumstances like chemotherapy or chronic illnesses, diseases such as Klinefelter syndrome, a genetic condition that occurs in males when they are born with an extra X chromosome, and late onset hypogonadism associated with aging. Low testosterone levels have repercussions, including reduced libido, infertility, obesity, diabetes type 2, and metabolic syndrome, with bidirectional interactions that question whether it is a cause or consequence of these conditions.

Current treatments predominantly involve exogenous testosterone replacement therapies (TRTs) in various formulations (gels, pills, injectables, etc.). Although it is established that TRTs are beneficial for treating certain symptoms of low testosterone, they can cause side effects such as suppression of natural testosterone production, infertility, elevated red blood cell counts, and elevated blood pressure.

In response to these challenges, Acesis BioMed is founding a fresh approach with its proprietary family of testosterone-inducing peptides. The Acesis' peptides under development are to be administered orally, in order to restore endogenous testosterone levels without introducing external hormones into the body. Preclinical testing has demonstrated that these peptides are bioactive at very low concentrations and are considered to be minimal in terms of side effects—claims that need



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- **Male Hypogonadism (Primary and Secondary):** Our current focus is to complete preclinical and IND, enabling studies in relevant animal models with the goal to transition to Phase 1 clinical trials.
- **Klinefelter syndrome (Certain Karyotypes could Qualify as Rare Disease):** Recognizing the unique needs of patients with rare conditions, Acesis aims to initiate partnerships with academic or private entities to obtain orphan drug designation and advance ACE-167 for these populations.
- **MASLD (Metabolic Dysfunction-Associated Steatotic Liver Disease), previously NAFLD:** Given the association between low testosterone levels and metabolic disorders, ACE-167 is being explored as a potential therapeutic option, with plans to collaborate with academic or industry partners.
- **Diabetes type 2 and Obesity:** With strong scientific evidence linking low testosterone to these conditions, Acesis is evaluating ACE-167's efficacy in these diseases, seeking strategic partnerships to facilitate development.
- **Cachexia (Cancer and HIV-related):** Addressing muscle wasting and weight loss in chronic illnesses, ACE-167's potential benefits are under investigation, with plans to engage with relevant stakeholders for advancement.

The development timelines for these indications vary, with male hypogonadism being the initial focus. Other indications, such as MASLD, diabetes type 2, obesity, and cachexia, are projected to progress as secondary targets and contingent upon securing additional funding and partnerships.

In summary, Acesis BioMed is developing innovative, non-steroidal treatment to address testosterone deficiency and its associated conditions. Through its unique peptide-based approach, the company aims to offer safer and more effective treatment options, potentially transforming the landscape of men's health.

### Dr. Costas Karatzas | A Short Bio

Acesis BioMed's leadership team brings a wealth of experience and expertise to the company's mission. Dr. Costas Karatzas, serving as Chief Executive Officer, has been instrumental in steering the company's strategic direction. With a background in business development and technology transfer, Dr. Karatzas has a proven track record of building strategic partnerships and driving innovation in the life sciences sector. His leadership is complemented by the scientific acumen of Dr. Vassilios Papadopoulos, Co-founder and Chair of Acesis' Scientific Advisory Board, who brings extensive expertise in steroidogenesis, which forms the foundation of Acesis BioMed's innovative therapeutic



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***"Acesis Biomed aims to develop a novel and effective alternative to traditional treatments by focusing on restoring the body's natural testosterone production processes."***

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