



Avadel Pharmaceuticals Provides 2017 Guidance and Business Update

January 5, 2017

Full Year 2017 Revenue Guidance of \$170 - \$200 million

Adjusted Diluted EPS of \$0.20 - \$0.35

DUBLIN, Ireland, Jan. 05, 2017 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (NASDAQ:AVDL), today announced 2017 financial guidance and outlined a number of key business objectives for the year, including successful completion of enrollment for the REST-ON Phase III clinical trial, its intention to pursue a fourth New Drug Application (NDA) for an unapproved marketed drug (UMD), AV001, the expansion of internal growth opportunities and the active pursuit of external acquisitions.

For the 2017 fiscal year, the Company has set forth the following financial expectations:

- Revenue in the range of \$170 - \$200 million
- An adjusted effective tax rate ranging from 70% – 80%*
- Adjusted diluted EPS in the range of \$0.20 - \$0.35*

Michael Anderson, Avadel's Chief Executive Officer, commented, "We are initiating 2017 revenue guidance of between \$170 to \$200 million and adjusted diluted EPS of between \$0.20 and \$0.35. This is a substantial increase over 2016, due largely to higher Akovaz™ revenues. The lower end of our revenue guidance assumes an additional competitor for each of our three sterile injectable products by mid-2017, while the top end of the range assumes competitors later in the year. Our diluted adjusted EPS includes an adjusted effective tax rate of 70% - 80%. Also, I am pleased to say that as a result of stronger than expected performance across our sterile injectable products since our last guidance update, we expect to finish 2016 near the top end of our revenue guidance of \$133 to \$143 million."

Mr. Anderson continued, "We have also seen promising growth in our pediatric products as measured by weekly IMS prescription trends and we believe we are at a turning point where we can begin to establish growth in this segment. Since having acquired the products in early 2016, we have improved our physician targeting, enhanced the management team, and have strengthened training within the sales force. With plans to launch our fourth product, Flexichamber®, late in the first quarter, the pediatric portfolio should be a more meaningful contributor in 2017."

In December 2016, the Company initiated patient enrollment and dosing for its REST-ON Phase III clinical trial to assess the safety and efficacy of its once nightly formulation of Micropump® sodium oxybate (FT218) for the treatment of excessive daytime sleepiness (EDS) and cataplexy in patients suffering from narcolepsy. The sole-source market for sodium oxybate, dosed twice nightly, is estimated at \$1.1 and \$1.125 billion in 2016, which represents a substantial market opportunity. Avadel believes that its product could offer significant advantages over the existing product to narcolepsy patients. Successful completion of enrollment by year-end 2017 remains a primary objective.

Mr. Anderson remarked, "We are entering 2017 on track to complete patient enrollment in REST-ON before the end of this year, and are pleased with the progression of continued clinical site initiations. The potential for FT218 to offer patients an improved quality of life over their current treatment, and to provide untreated patients relief of EDS and cataplexy, is tangible. We look forward to providing our stakeholders an update on enrollment sometime in mid-2017."

The Company also plans to pursue approval from the U.S. Food and Drug Administration (FDA) for a sterile, injectable unapproved drug product. Formulation development is underway, and the Company expects to file an NDA late in the fourth quarter of 2017. Based on current market assumptions the company believes the opportunity could provide revenue comparable to Vazculep® when it was launched. The Company has not included AV001 in its 2017 revenue guidance.

Mr. Anderson continued, "We are excited to announce pursuit of our fourth UMD, AV001. Unlike our first three products, AV001 and any future products we seek approval for, will not be subject to a gross-profit share with certain related parties. We are currently evaluating several other UMD opportunities for development. The company's UMD strategy has proved to be quite successful in its purpose – generating high margin cash flow. We have used this cash principally to acquire our branded pediatric business and to independently fund our proprietary projects. We will continue to look for strategic opportunities to deploy cash during 2017."

On September 30, 2016, Avadel had \$149.6 million in cash and marketable securities and no bank debt on its balance sheet. As a part of its growth strategy, Avadel is actively evaluating a number of commercial stage products and or companies to acquire, and to divest or out license two of its four platform technologies, Trigger Lock™ and Medusa™.

"For a Company of our size and resources, we are narrowing our focus to our two most developed platforms, Micropump® and LiquiTime®. We are pursuing the divestiture or out licensing of Trigger Lock™ for abuse deterrence, and Medusa™ for extended-release subcutaneous injection. We believe both platforms are robust and well protected from an IP standpoint; however, their development and approval would require substantial investments in clinical work and infrastructure, which we are not currently prepared to support," concluded Mr. Anderson.

About Avadel Pharmaceuticals plc:

Avadel Pharmaceuticals plc (NASDAQ:AVDL) is a specialty pharmaceutical company that seeks to develop differentiated pharmaceutical products that are safe, effective and easy to take through formulation development, by utilizing its proprietary drug delivery technology and in-licensing / acquiring new products; ultimately, helping patients adhere to their prescribed medical treatment and see better results. Avadel currently markets products in the hospital and primary care spaces. The Company is headquartered in Dublin, Ireland with operations in St. Louis, Missouri and Lyon, France. For more information, please visit www.avadel.com.

*Non-GAAP financial measure. Adjusted diluted EPS excludes, if any, fair value remeasurements of its contingent consideration, impairment and amortization of intangible assets, foreign exchange gains and losses, and certain other items, but includes the operating cash flows plus any unpaid accrued amounts associated with the contingent consideration. The adjusted effective tax rate excludes the tax impacts, if any, of the items excluded from adjusted diluted EPS.

Safe Harbor: This release may include "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements herein that are not clearly historical in nature are forward-looking, and the words "anticipate," "assume," "believe," "expect," "estimate," "plan," "will," "may," and the negative of these and similar expressions generally identify forward-looking statements. All forward-looking statements involve risks, uncertainties and contingencies, many of which are beyond Avadel's control and could cause actual results to differ materially from the results contemplated in such forward-looking statements. These risks, uncertainties and contingencies include the risks relating to: our dependence on a small number of products and customers for the majority of our revenues; the possibility that our Bloxiverz[®], Vazculep[®] and Akovaz[™] products, which are not patent protected, could face substantial competition resulting in a loss of market share or forcing us to reduce the prices we charge for those products; the possibility that we could fail to successfully complete the research and development for pipeline products we are evaluating for potential application to the FDA pursuant to our "unapproved-to-approved" strategy, or that competitors could complete the development of such product and apply for FDA approval of such product before us; our dependence on the performance of third parties in partnerships or strategic alliances for the commercialization of some of our products; the possibility that our products may not reach the commercial market or gain market acceptance; our need to invest substantial sums in research and development in order to remain competitive; our dependence on certain single providers for development of several of our drug delivery platforms and products; our dependence on a limited number of suppliers to manufacture our products and to deliver certain raw materials used in our products; the possibility that our competitors may develop and market technologies or products that are more effective or safer than ours, or obtain regulatory approval and market such technologies or products before we do; the challenges in protecting the intellectual property underlying our drug delivery platforms and other products; our dependence on key personnel to execute our business plan; the amount of additional costs we will incur to comply with U.S. securities laws as a result of our ceasing to qualify as a foreign private issuer; and the other risks, uncertainties and contingencies described in the Company's filings with the U.S. Securities and Exchange Commission, including our annual report on Form 10-K for the year ended December 31, 2015, all of which filings are also available on the Company's website. Avadel undertakes no obligation to update its forward-looking statements as a result of new information, future events or otherwise, except as required by law.

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