Avadel Pharmaceuticals Issues 2018 Corporate Outlook

December 29, 2017

Commercial launch for Noctiva™ on target for second quarter 2018

NDA filing for FT218 expected by year-end 2018

Total revenues expected to range from $110 - 130 million

DUBLIN, Ireland, Dec. 29, 2017 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (NASDAQ:AVDL), "Avadel" or "the Company," today announced its 2018 corporate objectives and financial expectations, including the commercial launch of Noctiva™ and the anticipated filing of a New Drug Application (NDA) for both FT218, a once-nightly formulation of sodium oxybate using Micropump®, and its fourth Unapproved Marketed Drug (UMD) product, AV001.

For 2018, the Company has set forth the following expectations:

- Implement a full-scale commercial launch for Noctiva during the second quarter
- File the NDA for FT218 by the end of 2018
- File the NDA for AV001, its fourth UMD product
- Maintain market leading position across its portfolio of hospital products and improve the effectiveness and efficiency of its pediatric operations
- Enhance portfolio development through selective M&A and advancement of internal pipeline
- Generate total revenues between $110 - $130 million

Mike Anderson, Avadel's Chief Executive Officer, remarked, "We are excited to enter 2018 with a set of strategic objectives that will be transformational for our company. Achievement of these objectives moves us towards our goal of becoming a fully integrated specialty pharmaceutical company with an exceptional long-term growth trajectory. We have built a strong base business that has provided and continues to provide us cash flow, and we have laid the groundwork to invest in our future."

Mr. Anderson continued, "We not only expect to successfully complete our Phase III REST-ON trial of FT218 for excessive daytime sleepiness and cataplexy, and subsequently file our NDA by year end, but we are also gearing up for a strong commercial launch for Noctiva™ in the second quarter. Both FT218 and Noctiva are proprietary products with enormous market potential. They will expand our commercial footprint into new therapeutic categories and create meaningful long-term value for shareholders."

Clinical Operations

Avadel is progressing in enrolling patients for its REST-ON Phase III clinical trial. REST-ON is a double-blind, randomized, placebo controlled study of 264 patients to assess the efficacy and safety of FT218, a once nightly formulation of sodium oxybate for extended-release oral suspension for the treatment of excessive daytime sleepiness (EDS) and cataplexy in patients suffering from narcolepsy. FT218 uses the Company's proprietary Micropump® drug delivery technology.

"Filing the NDA for FT218 by the end of 2018 is still our target, and strategies to drive enrollment through social media, clinical site incentive goals and identification of additional clinical sites have aided us in maintaining this objective. We recognize that enrollment is the most difficult aspect of this trial given the limited population of narcolepsy patients and the strict exclusion criteria agreed upon in our Special Protocol Assessment with FDA. The important thing is that we continue to make progress with patient enrollment and simultaneously prepare the nonclinical and CMC requirements for our NDA filing," said Mr. Anderson.

Mr. Anderson continued, "We maintain that FT218 is our most important clinical project in 2018. The opportunity to enter a possible blockbuster market with a potentially superior product is incredibly meaningful for our company. The current approved product to treat the condition generates well over $1 billion per year. Based on an independent claims analysis, there exists a large body of patients who ultimately choose not to remain on the approved twice-nightly version of sodium oxybate, with only 46% of new start patients persisting on treatment at twelve months[1]. The need and desire for a once-nightly product from the medical community and patients are strong, and we believe FT218 has the potential to meet these needs."

In addition to FT218, Avadel is also working to file an NDA for a fourth sterile injectable product, AV001, which is currently being marketed by another company without FDA approval. During the formulation and development work for AV001, the Company uncovered what it believes is a meaningful improvement to the product's safety profile. AV001 is expected to compete in an estimated market size of approximately $30 - $40 million per year once launched in 2019.

Commercial Operations

Noctiva™

In September 2017, Avadel in-licensed Noctiva, the first and only FDA approved product for nocturia due to nocturnal polyuria. Nocturnal polyuria is the overproduction of urine at night and leads to the condition of nocturia, which causes patients to wake two or more times per night to void. It is estimated that nocturia affects approximately 40 million[2] people in the United States and represents a large unaddressed and unmet medical need.

Greg Divis, Avadel's Chief Commercial Officer, said, "We are making great progress in executing our launch plans for Noctiva. We have completed hiring for all key roles, including an eighty person salesforce that will be out in the field as soon as late January to begin disease state education and initiating patient experience programs across urology specialists. We remain very pleased with the continued feedback we have received from physicians, patients and payers as it relates to Noctiva. Overall, we are confident that the work we have been doing will set us up for a successful commercial launch in the second quarter."

The Company estimates that peak revenues for Noctiva could be as high as $750 million or more per year.

Hospital Products

Avadel's three sterile injectable products, Akovaz® (ephedrine sulfate), Bloxiverz® (neostigmine methylsulfate) and Vazculep® (phenylephrine hydrochloride), ended 2017 as market share leaders for each of their respective categories. Akovaz and Bloxiverz were both subject to additional generic competitors late in the second half of 2017, and the Company expects increased pressure on both share and price as a result in 2018. Avadel remains committed to maintaining market leadership across its hospital products during 2018.

Mr. Divis said, "These hospital products were developed to provide the company with cash flow and they have exceeded our expectations. Despite the increasingly competitive environment for these generics, we have continued to maintain market leadership and strong gross margins across our portfolio, and we fully anticipate that these products will continue to be valuable assets to our company."

Pediatric Products

Avadel's pediatric products showed good growth during 2017 with Karbinal ER showing especially robust growth. Recent weekly prescription trends for Karbinal ER average approximately 1,800 TRxs per week, representing greater than 200% growth over 2016. In July, Flexichamber was launched and continues to grow slowly but steadily. The company's original plan for the pediatric business was to include additional products to add to those acquired from FSC Pediatrics. To date, the company continues to look for proprietary meaningfully differentiated products with growth potential to add into the portfolio.

2017 Outlook

The Company is reaffirming its 2017 revenue guidance to be in the range of $165 to $175 million and expects to be at the top end of its adjusted EPS guidance of $0.25 to $0.35.

2018 Financial Guidance

Due to the generic nature of its hospital business and recent increased competition, the Company expects revenues to decline on a year-over-year basis and anticipates generating between $110 - $130 million in revenues for 2018, including $10 - $20 million of Noctiva revenues. In preparation to reach its 2018 strategic objectives, the Company expects to invest heavily in both Research & Development (R&D) and Sales & Marketing. R&D costs are expected to range from $40 - $50 million, the majority of which will be incurred by the REST-ON trial and subsequent NDA filing. Selling, General & Administrative (SG&A) expense is expected to be in the range of $85 - $95 million. Included in SG&A is approximately $50 - $55 million of Selling & Marketing costs for Noctiva. Excluding these launch costs, SG&A is expected to be in the range of $35 – $40 million, down slightly from 2017. Given the revenue, R&D and SG&A spending expectations and a $20 million Noctiva launch milestone payment due by June 30, 2018, the Company expects negative cash flow in 2018. Currently, the Company has a strong balance sheet and as a matter of good corporate governance will continue to closely monitor its cash requirements and as required will take steps to ensure adequate liquidity to fund its strategic priorities. The Company is currently assessing the Tax Cuts and Jobs Act of 2017 and, accordingly, is unable to provide 2018 adjusted diluted EPS guidance; however, it does not believe it will be required to pay a significant amount of cash taxes during the year.

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. The Company is headquartered in Dublin, Ireland with operations in St. Louis, Missouri, United States and Lyon, France. For more information, please visit www.avadel.com.

About Noctiva™
Noctiva is the first and only formulation of desmopressin acetate, a vasopressin analog, approved by the FDA for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void. It is a proprietary low-dose formulation of desmopressin acetate administered through a patent-protected preservative-free intranasal delivery system. Noctiva is dosed as a single spray in one nostril 30 minutes before bedtime, and is approved in two dosage forms of 0.83 mcg and 1.66 mcg. Noctiva is expected to become available to patients in the second quarter of 2018. (Full Prescribing Information available here).

Important Safety Information and Indication for Noctiva (desmopressin acetate)

WARNING: HYPONATREMIA

- **NOCTIVA can cause hyponatremia. Severe hyponatremia can be life-threatening, leading to seizures, coma, respiratory arrest, or death.**

- **NOCTIVA is contraindicated in patients at increased risk of severe hyponatremia, such as patients with excessive fluid intake, illnesses that can cause fluid or electrolyte imbalances, and in those using loop diuretics or systemic**

or inhaled glucocorticoids.

- **Ensure serum sodium concentrations are normal before starting or resuming NOCTIVA. Measure serum sodium within seven days and approximately one month after initiating therapy or increasing the dose, and periodically during treatment. More frequently monitor serum sodium in patients 65 years of age and older and in patients at increased risk of hyponatremia.**

- **If hyponatremia occurs, NOCTIVA may need to be temporarily or permanently discontinued.**

Safe Harbor: *This press release may include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The words "will," "may," "believe," "expect," "anticipate," "estimate," "project" and similar expressions, and the negatives thereof, identify forward-looking statements, each of which speaks only as of the date the statement is made. Although we believe that our forward-looking statements are based on reasonable assumptions within the bounds of our knowledge of our business and operations, our business is subject to significant risks and as a result there can be no assurance that actual results of our research, development and commercialization activities and our results of operations will not differ materially from the results contemplated in such forward-looking statements. These risks include: (i) risks relating to our license agreement with Serenity Pharmaceuticals, LLC including that our internal analyses may overstate the market opportunity in the United States for the drug desmopressin acetate (the "Drug") or we may not effectively exploit such market opportunity, that significant safety or drug interaction problems could arise with respect to the Drug, that we may not successfully increase awareness of nocturia and the potential benefits of the Drug, and that the need for management to focus attention on the development and commercialization of the Drug could cause our ongoing business operations to suffer; and (ii) 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, 2016, in particular under the captions "Forward-Looking Statements" and "Risk Factors," including without limitation: 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 products and apply for FDA approval of such products before us; 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; and our dependence on key personnel to execute our business plan. Except as may be required by law, we disclaim any obligation to publicly update any forward-looking statements to reflect events after the date of this press release.*

Non-GAAP Disclosures and Adjustments

Avadel discloses certain non-GAAP financial measures, including adjusted net income and loss and adjusted net income and loss per diluted share, as management believes that a comparison of its current and historical results would be difficult if the disclosures were limited to financial measures prepared only in accordance with generally accepted accounting principles (GAAP) in the U.S. In addition to reporting its financial results in accordance with GAAP, Avadel reports certain non-GAAP results that exclude, if any, fair value remeasurements of its contingent consideration, impairment of intangible assets, amortization of intangible assets, restructuring costs, foreign exchange gains and losses on assets and liabilities denominated in foreign currencies, but includes the operating cash flows plus any unpaid accrued amounts associated with the contingent consideration, in order to supplement investors' and other readers' understanding and assessment of the Company's financial performance. The Company's management uses these non-GAAP measures internally for forecasting, budgeting and measuring its operating performance. Investors and other readers should review the related GAAP financial measures and the reconciliation of non-GAAP measures to their most closely applicable GAAP measure set forth below and should consider non-GAAP measures only as a supplement to, not as a substitute for or as a superior measure to, measures of financial performance prepared in accordance with GAAP. The table provided within the following "Supplemental Information" section reconciles GAAP net income and loss and diluted earnings or loss per share to the corresponding adjusted amounts.

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[1] Data on file.

[2] Sources: (1) US census data 2016 estimates (2) Lee, L. K., et al. "Potential benefits of diagnosis and treatment…" International journal of clinical practice 70.1 (2016): 66-81.

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Avadel Pharmaceuticals plc