Large Volume Wearable Injectors Market (3rd Edition), 2017-2027

Description: Drug delivery systems optimized to provide flexibility in dosing regimen, reduce the number of hospital visits, decrease dependence on healthcare professionals and enhance adherence to the therapeutic regimen have become the preferred choice of drug administration.

The large scale adoption of prefilled syringes, the first ready-to-use injection device to be marketed, demonstrated the growing interest in the concept of such convenient drug delivery systems. In addition, several pen-injectors and autoinjectors have witnessed an impressive growth in the recent past. However, these hand-held devices are only capable of administering drugs with dosing volume close to 1 ml. With over 900 biologics being developed (most of these are highly viscous and are required to be delivered in volumes greater than 1 ml), there is a growing demand for self-administration devices than can overcome this unmet need.

Large volume wearable injectors, an advanced version of the existing self-injection devices, are expected to gather interest from a wide customer base. In fact, there are a number of such injectors commercially available for delivery of insulin. OmniPod, from Insulet Corporation, is a very well-known device that has generated significant year-on-year revenue growth. However, it is worth highlighting that till date only one large volume wearable injector (SmartDose Electronic Wearable Injector) has been approved for administration of a non-insulin biologic. Despite the uncertainties related to the device development and approval, many companies are investing their time, money and resources to develop these novel devices. In addition to the publically known programs, pharma companies have many undisclosed programs that are likely to provide the necessary growth impetus in the long term.

It is worth noting that the VC community has demonstrated significant interest in funding projects related to such wearable injectors. These investments are expected to drive further innovation and lead to the introduction of novel device candidates in the industry. Quite recently, in January 2017, scPharmaceuticals closed a series B investment round worth USD 45.6 million. The company intends to use the funding to bring Furoscix and the sc2Wear Infusor to the market in the US. Earlier, in July 2016, SteadyMed Therapeutics raised USD 32 million in a private placement round financed by Deerfield Capital Management, Federated Investors and OrbiMed. In September 2015, CeQur completed a USD 100 million Venture (Series C) financing round, which was led by Woodford Investment Management, Arthurian Life Sciences, Endeavour Vision, VI Partners and Schroders.

Several partnerships have also been inked in this domain in the last few years. Most of these are focused on the development/commercialization of a variety of wearable injectors. Such partnerships are important for technological integration, supply of devices and also facilitate the conduct of clinical trials related to drug-device combination products. We believe that the device developers will continue to strive to introduce unique and user-friendly features into their proprietary range of devices. The upgradation of existing devices to more competent/next generation devices will serve as a key driver of immediate near-term growth.

The "Large Volume Wearable Injectors Market (3rd Edition), 2017-2027" report features an extensive study of the current landscape and the likely future evolution of this category of drug delivery devices over the next ten years. With the increasing incidence of chronic and lifestyle-related diseases across the globe, the demand for efficient drug delivery systems is growing at a rapid pace. In order to simplify the process of drug delivery, eliminate costs and reduce the incidence of needlestick injuries, the pharmaceutical industry has shifted its focus towards the development of self-injection devices for parenteral drugs/therapies. This report specifically lays emphasis on the emergence of such patient-centric, convenient, cost-effective and user-friendly wearable injectors that are capable of administering large volumes of a drug subcutaneously in a home-care setting.

It is worth noting that the concept behind such injectors is being widely employed for the delivery of insulin. Over 15 such unique series of injectors (excluding variants) have already entered the market. On the other hand, there is only one large volume wearable injector (mentioned above) approved for the administration of a non-insulin biologic in the US. However, with a variety of biologics under investigation, we believe that device developers have a significant opportunity waiting to be tapped. The field is likely to pick up momentum in the next few years. In fact, an increase in the partnerships and investment activities demonstrate that the market is geared towards significant growth in the mid to long term.
One of the key objectives outlined for the study was to evaluate the future potential of the ongoing development programs of both big and small firms. Among other elements, the report elaborates on the following areas:

- An overview of the current market landscape in terms of the key players involved, development status of pipeline products (marketed/under development), type of dose (bolus/continuous/both), usability (disposable/reusable) and key indications.
- Detailed profiles of large volume wearable devices that are being developed for the delivery of biologics (including insulin), highlighting their key features, current status of development, recent developments and associated collaborations.
- An exhaustive review of over 300 biologics, which are potential candidates for delivery using large volume wearable injectors. The molecules/therapies have been categorized into most-likely, likely and less-likely candidates for administration using large volume wearable injectors. This categorization is based on various parameters including recommended volume, route of administration, frequency of the dose, standard/weight based dose and the chronicity of target indication.
- Comprehensive case studies on drugs that are being evaluated for delivery via large volume wearable injectors, highlighting their specifications, mechanisms of action, current status of development, sales, respective dosages and any other recent developments.
- An illustrative grid representation of the devices based on the category of device (insulin/non-insulin biologic), type of dose and type of device (infusion pump/patch pump). In addition, the report includes an insightful 2 X 2 matrix analysis, highlighting the positioning of the devices based on product competitiveness and supplier power.
- A discussion on the key drivers and challenges, in terms of the strengths, weaknesses, opportunities and threats (SWOT), which are likely to impact the future growth of this upcoming area.

The study provides a detailed market forecast and opportunity analysis for the period between 2017 and 2027. The research, analysis and insights presented in this report include potential sales of the drug-device combinations that are being evaluated and are anticipated to enter the market in the next few years. To add robustness to our model, we have provided three market forecast scenarios, namely the conservative, base and optimistic scenarios. It is worth noting that, although the market of insulin delivery devices is relatively more mature, we have included a high-level opportunity analysis on the large volume wearable injectors being developed for delivery of insulin as well.

Our opinions and insights presented in this study were influenced by discussions conducted with several experts in this area. Specifically, we solicited the opinions of senior representatives including Menachem Zucker (VP and Chief Scientist, Elcam Medical), Michael Hooven (CEO, Enable Injections), Ben Moga (President, Ratio Drug Delivery), Pieter Muntendam (President and CEO, scPharmaceuticals), Graham Reynolds, (VP and GM, Biologics, West Pharmaceutical Services) and Tiffany H. Burke (Director, Global Communications, West Pharmaceutical Services). All actual figures have been sourced and analyzed from publicly available information forums and primary research discussions. The financial figures mentioned in this report are in USD, unless otherwise specified.

Example Highlights

- There are over 50 different large volume wearable injectors (including variants) that are either commercialized or are under development. Of these, around 60% are for delivery of insulin and the rest are for delivery of other biologics. Of the devices being developed for delivery of non-insulin biologics, SmartDose Electronic Wearable Injector (by West Pharmaceutical Services) has already received approval by the USFDA for delivery of Repatha.
- There are several other known references of drug-device combinations that are being evaluated in clinical studies; examples include SteadyMed Therapeutics' PatchPump (with Treprostinil and Ketorolac), NeuroDerm's CRONO ND (with NDO612 and NDO712), Roche's Single-use injection device (with Herceptin) and scPharmaceuticals's scWear Infusor (with Ceftriaxone and Furosemide).
- The commercially available insulin-based large volume wearable injectors can accommodate volumes of up to 5 ml. OmniPod, from Insulet Corporation, is a very well-known device that has generated significant year-on-year revenue growth. However, with improved design, several devices with capacity of holding up to 20 ml drug are being developed for delivery of biologics. In fact, over 50% of the devices that we identified for administration of non-insulin biologics have the capability of carrying 5-20 ml drug while 16% of these devices can hold over 20 ml drug.
- Our analysis suggests that close to 100 biologics (marketed/under development) are suited for delivery via large volume wearable injectors and are likely to be evaluated in different drug-device combinations in the near future. These biologics (full list available in the main report) are designed for treatment of chronic
conditions, which require frequent dosing, and are not currently available in suitable self-administration systems. We believe that some of these drugs, if tested and approved with large volume wearable injectors, are likely to make a substantial contribution to the market's evolution in the mid-long term.
- Innovation in the field is primarily being driven by start-ups/small companies; examples of firms working for delivery of non-insulin biologics include (in alphabetical order) Elcam Drug Delivery Systems, Enable Injections, NeuroDerm, scPharmaceuticals, Sensile Medical. Notable examples of start-ups that have taken initiatives for delivery of insulin include Cellnovo, CeQu, Debiotech, PicoSulin, SOOIL and ViCentra. In addition, a number of large companies are making notable contribution in this field; prominent players include Becton Dickinson, Johnson & Johnson, Medtronic, Roche and West Pharmaceutical Services.
- Several other companies engaged in this domain have reported positive clinical outcomes of their drug-device combinations. scPharmaceuticals is expecting the commercial launch of its two product candidates for the drugs furosemide and cephalosporin in 2017/18. In addition, Neuroderm and SteadyMed Therapeutics are also hopeful of making their products commercially available in the near future. At the same time, insulin delivery devices, such as OmniPod, are now also being explored for the delivery of non-insulin drugs, such as the gonadotropin-releasing hormone developed by Ferring Pharmaceuticals.
- The overall market for large volume wearable injectors is likely to grow at an aggressive rate of over 150%. We believe that OmniPod will continue to lead the market for insulin delivery. However, majority of the growth is likely to come from drug-device combinations under trials for non-insulin biologics. In our base scenario, we have predicted that the annual sales volume of such devices could be over 40 million units by 2027.

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