

Bleeding Disorders: World Pharmaceutical Industry and Market 2014-2024

Between 2012 and 2018, revenue generated by sales of Helixate will increase at a CAGR of 0.16%. Between 2018 and 2024, revenue will decrease at a CAGR of -1.5%. In 2024, sales of the drug will generate \$463m, accounting for 2.67% of the total market.

4.11 Nplate: The Leading Product for Thrombocytopenia in 2012

Table 4.18 Nplate: Key Facts

Drug	Nplate (romiplostim)	
Company	Amgen	
Approval Date	US	Aug-08
	EU	Feb-09
Indication	Thrombocytopenia	
Route of Administration	Injection	
Revenue (\$m)	2012	368
	2011	297
	2010	229
Patent Expiry	US	Jan-22
	EU	Oct-19

Source: *visiongain 2013*

Nplate is marketed by Amgen. It was approved by the FDA in August 2008 and by the EMA in February 2009 for the treatment of thrombocytopenia in adults with idiopathic thrombocytopenic purpura, an autoimmune disease. It is a fusion protein analogue of thrombopoietin, a naturally occurring hormone which regulates platelet count. Nplate works by raising and sustaining the blood platelet count using the same mechanism of action as this hormone. Upon its launch, it represented a novel therapeutic approach to thrombocytopenia in this patient population.

In 2012, sales of Nplate generated \$368m. The product has seen strong annual growth in recent years. Driving this strong revenue generation is the chronic nature of the disease, which requires long term treatment, generating repeat sales. Additionally, Amgen is licensed to market Nplate in the US, all of Europe, Canada, Australia, New Zealand, Mexico, all Central and South American countries and certain countries in Africa, Asia and the Middle East meaning the drug is available to a large patient population. After approval, Nplate was subject to restricted distribution as a result of safety concerns arising from the limited experience with the drug. However, these Risk Evaluation and Modification Strategies (REMS) were modified in December 2011; prescribers, healthcare institutions, pharmacies and patients no longer have to enroll in REMS programmes in order to prescribe, dispense or take these drugs. This modification has resulted in an expanding market for Nplate.

Amgen is conducting clinical trials with Nplate in the treatment of thrombocytopenia caused by hepatitis C, multiple myeloma and other cancers (chemotherapy-induced). Indication expansions

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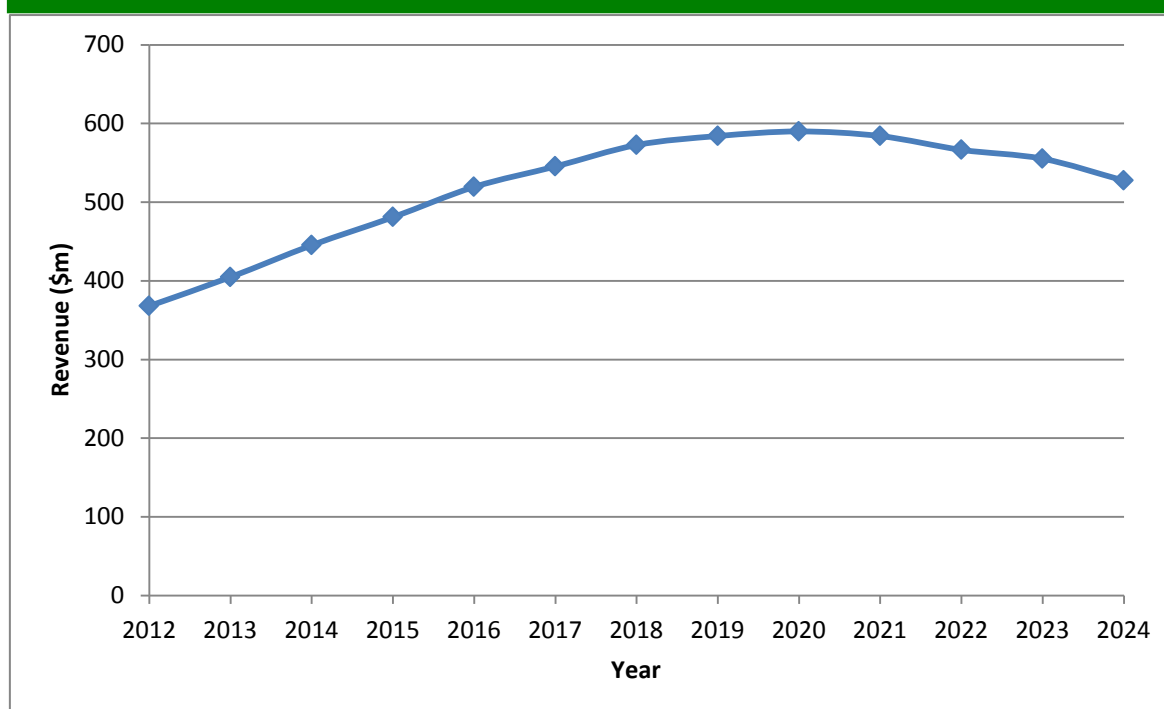
will also result in an expanding market for Nplate. As a result of these factors, revenue generated by Nplate will see strong growth until 2016. Between 2012 and 2018, revenue generated by Nplate will expand at a CAGR of 7.65%. However, Nplate competes directly with GlaxoSmithKline's Promacta and from 2016 onwards, the annual rate of growth in revenue will begin to decline as a result of market saturation.

Table 4.19 Nplate: Revenue (\$m) and Market Share (%) Forecast, 2013-2024

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
Market Share (%)	3.61	3.74	3.90	3.97	4.06	4.04	4.03	3.91	3.76	3.62	3.46	3.30	3.05
Revenue (\$m)	368	405	445	481	519	545	573	584	590	584	566	555	527
AGR (%)		10	10	8	8	5	5	2	1	-1	-3	-2	-5
CAGR (%)							7.65						-1.36

Source: *visiongain 2013*

Figure 4.11 Nplate: Revenue Forecast (\$m), 2013-2024



Source: *visiongain 2013*

Revenue generated by Nplate will peak in 2020 at \$590m, accounting for 3.76% of the total bleeding disorders market. From 2021 onwards competition in the market will result in negative annual growth. Between 2018 and 2024, revenue will decrease at a CAGR of -1.36%. In 2024, sales of Nplate will generate \$527m, accounting for 3.05% of the total market.