

### Phase III Stage Product Development Costs

These are interim costs; the products in this section are still in development and will surely incur additional expenses. The Phase I and II costs in Table 8-2 should be close (assuming the products are eventually approved), while the Ph III costs only partially reflect the total costs.

These costs are not as high as those presented in Table 8-1, but these products have not yet reached approval, and it's not clear if the lower mean and median investments in Phase I and II (Phase III costs are not yet complete) will impact their chance of approval. This data suggests it is possible to conduct a Phase I and II development program for less; but not necessarily successfully.

**Table 8-2: Phase III Stage Products, Mean and Median Direct Costs**

	Number of Products	Mean Average Cost	Median Cost
Phase I + Phase II Costs	5	\$17,499,000	\$8,235,000
Phase III Costs (Ongoing)	5	\$29,784,000	\$30,974,000
Development Costs to Date	5	\$47,283,000	\$39,209,000
Phase IV Costs	N/A	N/A	N/A

The products in Table 8-2 include one pulmonary, two intranasal, one topical and one injectable formulation. All five products incorporate previously approved actives.

### Direct Development Cost Summary

The quick take away is that a company should budget about \$20 million in direct costs to conduct a Phase I and II program for a drug delivery product that has the potential to reach approval. Direct costs in this case include amounts paid to third party providers and suppliers as well as internal costs directly related to conducting the development program. It would not include general overhead, management supervision and facility expenses.

Direct Phase III development costs seem to run in the range of \$60 to \$70 million. This is a much higher figure than most companies expect when they enter into the development process. (It may also help explain why there is such a low Phase II to Phase III transition rate, Chapter 5. Without adequate funding these expenses are beyond the reach of most drug delivery companies.) The two approved pulmonary products included in Table 8-1 had Phase III only development costs of about \$100 million in 2009 dollars.