

A security breach that impairs these distribution or logistics operations could significantly impair our ability to deliver our products to healthcare providers. In addition, our products are manufactured and tested by third parties, and a security breach that impairs these third parties could significantly impair our ability to procure our products and deliver them to our distributors in a timely manner. There can be no assurance that our or their efforts will detect, prevent or fully recover systems or data from all breakdowns, service interruptions, attacks or breaches of systems, any of which could adversely affect our business and operations and/or result in the loss of critical or sensitive data, which could result in financial, legal, business or reputational harm to us or impact our stock price.

In addition, the loss of clinical trial data for our product candidates or our post-market studies could result in delays in our regulatory approval efforts or marketing efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions or security breaches of our internal information technology systems or our vendors' technology systems could adversely affect or result in the loss of, misappropriation of, unauthorized access to, use of, disclosure of or the prevention of access to our confidential information, including trade secrets or other intellectual property, proprietary business information and personal information of our employees and patients in studies conducted on our behalf, which could result in financial, legal, business and reputational harm to us. For example, any such event that leads to unauthorized access to, use of or disclosure of personal information, including personal information regarding our employees or information we may have regarding patients, could harm our reputation directly, compel us to comply with federal and state breach notification laws and foreign law equivalents, subject us to mandatory corrective action and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Maintaining and growing our commercial infrastructure is a significant undertaking that requires productive, well-trained sales and marketing personnel, effective managers and substantial financial resources, and we may not be successful in our efforts to meet these needs.

We anticipate that in the near term our ability to generate revenues will depend almost entirely on our ability to continue the successful commercialization of our current products, both in the U.S. and internationally. A commercial launch of our current products is a significant undertaking that requires substantial financial and managerial resources. As our commercialization plans and strategies evolve, we will need to further expand the size of our organization by recruiting additional managerial, operational, sales, marketing, financial and other personnel.

We may not be able to maintain and expand our commercial operation in a cost-effective manner or realize a positive return on this investment. In addition, we have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize our current products or any future products include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel or maintain our sales and marketing infrastructure;
- our inability to successfully enter into additional collaboration arrangements with third parties;
- the inability of sales personnel to obtain access to or persuade adequate numbers of ophthalmologists to prescribe our products;
- the lack of complementary products or additional labeled indications for our current products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with maintaining and growing a commercial organization.

Additionally, we may encounter unexpected or unforeseen delays in expanding our commercial operations that delay the commercial launch in one or more countries in which our current products have received marketing authorizations. These delays may increase the cost of, and the resources required for successful commercialization of our current products. Further, a delay in the commercial launch of our current products in certain jurisdictions could result in the withdrawal of our marketing or regulatory authorization for our current products in those jurisdictions, including certain EEA member states where our current products have already received marketing authorizations.

Clinical trials for our products may not generate the outcomes we expect, may take longer or be more costly to complete than we anticipate.

From time to time, we initiate or participate in clinical trials for our products and may in the future participate in clinical trials or studies for other products. The timing of patient enrollment in these trials, and related costs, can be unpredictable, and any such trials or studies may be more expensive or take longer than we expect. Data from clinical trials are not always conclusive. Even if successful, these studies and trials may fail to change physician prescribing practices.