The human immune system can go awry, either attacking an individual’s body or producing an exaggerated response to a foreign substance that is normally benign. In these situations, immunotherapies are needed to balance or suppress the unwarranted immune response. In this report:

- Approximately 400 product candidates and development programs are identified.
- Current and emerging therapies for selected autoimmune or inflammatory disorders and prevention of organ transplant rejection, directed against a wide range of putative targets, are summarized.
- Specifically, more than 250 emerging autoimmune disease therapies, 80 asthma therapies in development, and 50+ therapy candidates for allergies are covered.
- The strategic consequences of intense competition in a crowded product space are considered.

Continued on next page
**Inflammatory Disorders: Therapies That Suppress or Balance the Immune Response** reviews the problems of insufficient efficacy, side effects, and adverse events associated with the small-molecule and biological drugs available today to treat these disorders. These observations have led to an interest in identifying ways to balance the immune reaction, to suppress the part of the immune response that is causing the disease, while maintaining or enhancing other aspects of the immune system. This report identifies nearly 400 ongoing product candidates and development programs in these indication areas. The companies active in these areas range from multinational pharmaceutical companies with a number of active programs to small boutique start-ups working on a very defined topic.

Many of these programs involve “new” targets as well as a range of small-molecule and biological candidate therapeutics. The result is an extremely active, industry-wide product development race. As this report points out, this level of development activity for products addressing indications that frequently have quite limited patient populations is likely to lead to several rounds of ruthless attrition among these programs. Under such overheated conditions, the patient is likely to be less well served by innovation.

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**About the Author:** Lucy J. Sannes, PhD, MBA, is president of Sannes & Associates, a consulting firm specializing in evaluation and management of the biosciences. Before forming Sannes & Associates, she held management positions at Genetic Systems and Abbott Laboratories in product development, product support, and technical marketing. Dr. Sannes received her PhD in biological chemistry from the University of Michigan and her MBA from Seattle Pacific University.

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**Table 9.2. Selected Companies Developing Therapies for Autoimmune Diseases, Asthma, Allergies, and/or Prevention of Organ Transplant Rejection**

<table>
<thead>
<tr>
<th>Company</th>
<th>Emerging Therapy</th>
<th>Status</th>
<th>Indication(s) in Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott</td>
<td>Humira</td>
<td>On the market</td>
<td>FDA approved for treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriasis, ulcerative colitis, Crohn's disease, and mild to moderate atopic dermatitis</td>
</tr>
<tr>
<td>Abbott</td>
<td>ABT-404</td>
<td>Phase III</td>
<td>FDA approved for psoriatic arthritis</td>
</tr>
<tr>
<td>Abbott</td>
<td>Patenon</td>
<td>Not yet available</td>
<td>For psoriasis</td>
</tr>
</tbody>
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