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**CENTER** FOR ACCELERATING  
**INNOVATION AND IMPACT**  
USAID | GLOBAL HEALTH

# PATHWAYS TO SCALE

Toolkit for shaping a pathway to scale –  
Exercise worksheets and examples



From CII's IDEA to IMPACT Series

USAID's **Center for Accelerating Innovation and Impact (CII)** takes a business-minded approach to fast-tracking the development, introduction, and scale-up of health interventions that address the world's most important health challenges. CII invests seed capital in the most promising ideas, using the most forward-looking business practices to cut the time to transform discoveries in the lab to impact on the ground.



Pathways to Scale aims to help early-stage innovators develop business models and partnership approaches that align with the development of their products, and envision potential pathways to bring products to scale.

It introduces the most commonly found models for scaling up global health innovations, and features case studies that highlight and explain pathways taken by innovations that have begun to scale-up. It also offers a toolkit with exercises, structured questions, key considerations, and curated resources that innovators can use to identify the most suitable scaling model(s) to forge their path.

Questions and comments are welcome and can be directed to [cii@usaid.gov](mailto:cii@usaid.gov).

For contact information and to download the latest version of *Pathways to Scale*, please visit [www.usaid.gov/cii](http://www.usaid.gov/cii).

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We developed three exercises to help innovators assess the capabilities and resources needed to scale-up their innovation, identify the scaling model most suited to them, and raise the right questions for shaping a pathway to scale. We recognize that given the ambiguities inherent in early-stage innovations, such as the exact location of the target market, or target users' precise needs, innovators cannot provide accurate answers to some components of these exercises. To address this challenge, we have provided examples where possible, such as completed worksheets using Brilliance from the perspective of D-Rev. We encourage innovators to seek a mentor with experience in a similar industry/market to go through the exercises with them, and to revisit the exercise when new information becomes available, or when they achieve a significant milestone.



### **Exercise 1: Assess the capabilities and resources you need to scale-up**

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- Based on the profile of your innovation and your understanding of the capabilities and resources needed to bring it to scale, identify your gaps.
- Your answer will inform your choices and considerations in Exercises 2 and 3.



### **Exercise 2: Select appropriate scaling model(s)**

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- Determine the “best fit” scaling model for you and your innovation, based on:
  - How feasible it would be for you to pursue and implement each of the five scaling models
  - Your preferences



### **Exercise 3: Understand the key considerations for the chosen scaling model(s)**

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- Explore key questions and considerations for your chosen scaling model (identified in Exercise 2)
- Answers could be used to create a blueprint for your pathway to scale

Download the latest version of the Pathways to Scale exercises at [www.usaid.gov/cii](http://www.usaid.gov/cii).



## EXERCISE 1: ASSESS CAPABILITIES AND RESOURCES NEEDED FOR SCALE-UP

This toolkit begins with Exercise 1, aimed at helping innovators assess the scale-up capabilities and resources needed, given five dimensions of their product's profile, and identify gaps to meeting those needs on their own. This gap analysis helps inform the feasibility and preference considerations in Exercise 2 when innovators choose among potential scaling models, and also provides an important set of insights to help answer questions related to how innovators might pursue a chosen scaling model.

Exercise 1 has three sequential components: Part A, B and C. Each part builds on the previous piece and is explained below.

### A

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**Identify where your product falls along five key dimensions that impact the capabilities and resources required for scale-up**

In Part A, product profile mapping, the innovator identifies where his/her product falls along five key dimensions that impact the capabilities and resources required for scale-up. We identified these five dimensions as the most important drivers in deciding necessary capabilities for scale-up, and validated this framework with global health innovators, thought leaders, and other donors and investors.

### B

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**Given your product profile and the corresponding capabilities and resources required for scale-up, assess your abilities to meet these scaling requirements alone**

A product's characteristics along the five dimensions imply different capabilities and levels of funding needed for scale-up. In Part B, we developed a checklist of capability and resource requirements for each dimension. Using the product mapping results from Part A, innovators can use the checklist to assess their organization's ability to meet these scaling requirements alone.

### C

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**Synthesize the results of Part B to identify need for accessing/convening capabilities and resources from outside parties to fill gaps**

In Part C, the innovator will summarize the capability and resource gaps identified in Part B, and develop an assessment of the need to work with external actors on the scale-up journey. This 1-page worksheet is a synthesis of Exercise 1.



# Worksheet: Product Profile Mapping

**Purpose:** Identify where your innovation falls along five key dimensions that impact the capabilities and resources required for scale-up

**Instruction:** Select which product characteristic better describes your innovation along each dimension

Product profile dimensions	Scaling activities impacted	Product characteristics
<b>i</b> Degree of acceptance among users and other stakeholders	Ensure user acceptance and generate demand; ensure adoption within policy	<input type="checkbox"/> <b>Low acceptance hurdle</b> (existing market with healthy user demand; minimal user education or behavioral change required; no need for policy change) <input type="checkbox"/> <b>High acceptance hurdle; aka “paradigm shift”</b> (limited existing demand; significant user education and behavioral changes required; need to change policies)
<b>ii</b> Structure of buyer market (can select more than 1)	Acquire buyers and negotiate sales	<input type="checkbox"/> <b>Very consolidated market of one or a few donor procurers</b> <input type="checkbox"/> <b>Fragmented market of provider purchasers</b> (non-public and/or public) <input type="checkbox"/> <b>Consolidated market of large buyers</b> (often public or NGOs) <input type="checkbox"/> <b>Very fragmented market as buyers</b>
<b>iii</b> Complexity of clinical & regulatory needs	Complete clinical trials and obtain regulatory approval	<input type="checkbox"/> <b>Low complexity</b> (simple clinical/regulatory pathways; few regulatory approvals needed) <input type="checkbox"/> <b>High complexity</b> (extensive/ambiguous clinical/regulatory pathways; many national regulatory approvals needed)
<b>iv</b> Complexity of manufacturing & supply chain	Establish high-quality, cost-efficient manufacturing	<input type="checkbox"/> <b>Low complexity</b> (simple manufacturing process; easy to scale with a single manufacturer; many potential options) <input type="checkbox"/> <b>High complexity</b> (highly specialized manufacturing process; require multiple suppliers & manufacturers; limited options)
<b>v</b> Complexity of distribution & servicing	Provide needed distribution and servicing to buyers and/or users	<input type="checkbox"/> <b>Low complexity</b> (no need for a distribution/logistics network; minimal requirements for servicing) <input type="checkbox"/> <b>High complexity</b> (need extensive distribution/logistics network; significant requirements for locally-based servicing)

# Worksheet: Capabilities and resources required to ensure acceptance among users and other stakeholders

\$ = <\$10,000  
 \$\$ = \$10,000-\$100,000

\$\$\$ = \$100,000-\$1M  
 \$\$\$\$ = >\$1M

Purpose: Given product profile, understand capabilities and resources required to scale-up product, and which capabilities you are able to develop in-house

Instruction: For the product characteristic that better describes your innovation (those already mapped out in step 1A), select capabilities you already have in-house or would likely be able to organically develop

	Capabilities required	Resources required	Time frame <sup>1</sup>
<b>Low acceptance hurdle</b> (existing market with healthy user demand; minimal user education or behavioral change required; no need for policy change)	<ul style="list-style-type: none"> <li>▣ Minimal to no end user training/ education capacity required</li> <li>▣ Minimal to no capabilities required to effect policy/guideline changes for adoption of innovation</li> <li>▣ Minimal long term adjustment of messaging of value proposition</li> </ul>	<ul style="list-style-type: none"> <li>▣ \$-\$\$</li> </ul>	<ul style="list-style-type: none"> <li>▣ &lt; 1 yr</li> </ul>
<b>High acceptance hurdle; aka “paradigm shift”</b> (limited existing demand; significant user education and behavioral changes required; need to change policies)	<ul style="list-style-type: none"> <li>▣ Ability to generate and tailor relevant efficacy data and messages to stakeholders and key influencers</li> <li>▣ Capabilities to train end users</li> <li>▣ Ability and channels to effectively convey messaging and value proposition tailored to end user groups</li> <li>▣ Ongoing capacity to monitor and adjust product and messaging</li> </ul>	<ul style="list-style-type: none"> <li>▣ \$\$\$-\$\$\$\$</li> </ul>	<ul style="list-style-type: none"> <li>▣ &gt; 1 yr + ongoing support</li> </ul>

<sup>1</sup> Time frame associated with a market leader, could take longer depending on internal expertise and capabilities; findings based on expert interviews. Resources and time frame are directional only (not intended to be precise).







# Worksheet: Capabilities and resources required to acquire buyers and negotiate sales

\$ = <\$10,000  
\$\$ = \$10,000-\$100,000

\$\$\$ = \$100,000-\$1M  
\$\$\$\$ = >\$1M

Purpose: Given product profile, understand capabilities and resources required to scale-up product, and which capabilities you are able to develop in-house

Instruction: For the product characteristic that better describes your innovation (those already mapped out in step 1A), select capabilities you already have in-house or would likely be able to organically develop

	Capabilities required	Resources required	Time frame <sup>1</sup>
Very consolidated market of one or a few donor procurers	<ul style="list-style-type: none"> <li>Ability to negotiate with single or few stakeholders</li> <li>Deep knowledge of procurement processes</li> </ul>	<ul style="list-style-type: none"> <li>\$-\$\$</li> </ul>	<ul style="list-style-type: none"> <li>1 yr</li> </ul>
Consolidated market of large buyers (often public or NGOs)	<ul style="list-style-type: none"> <li>Capabilities and personnel to address buying needs of multiple governments and large provider networks</li> <li>Personnel to navigate contracts (tenders) with several stakeholders</li> <li>Limited sales force to address small number of buyers</li> </ul>	<ul style="list-style-type: none"> <li>\$\$-\$\$\$\$</li> </ul>	<ul style="list-style-type: none"> <li>1 yr</li> </ul>
Fragmented market of provider purchasers (non-public and/or public)	<ul style="list-style-type: none"> <li>Capabilities and personnel to address buying needs and contracts with a large number of diverse stakeholders</li> <li>Path and skills to create a recognizable and trusted brand</li> <li>Moderate size sales force to address numerous buyers</li> </ul>	<ul style="list-style-type: none"> <li>\$\$-\$\$\$\$</li> </ul>	<ul style="list-style-type: none"> <li>1 yr</li> </ul>
Very fragmented market of individual consumers as buyers	<ul style="list-style-type: none"> <li>Path and skills to create a recognizable trusted brand</li> <li>Ability to create and implement consumer advertising and marketing campaigns</li> <li>Potential need for a large size sales force</li> </ul>	<ul style="list-style-type: none"> <li>\$-\$\$\$\$</li> </ul>	<ul style="list-style-type: none"> <li>1 yr</li> </ul>

<sup>1</sup> Time frame associated with a market leader, could take longer depending on internal expertise and capabilities; findings based on expert interviews. Resources and time frame are directional only (not intended to be precise).



# Worksheet: Capabilities and resources required to complete clinical trials and obtain regulatory approval

\$ = <\$10,000  
 \$\$ = \$10,000-\$100,000

\$\$\$ = \$100,000-\$1M  
 \$\$\$\$ = >\$1M

**Purpose:** Given product profile, understand capabilities and resources required to scale-up product, and which capabilities you are able to develop in-house

**Instruction:** For the product characteristic that better describes your innovation (those already mapped out in step 1A), select capabilities you already have in-house or would likely be able to organically develop

	Capabilities required	Resources required	Time frame <sup>1</sup>
<b>Low complexity</b> (simple/established regulatory and R&D pathways; few regulatory approvals needed)	<ul style="list-style-type: none"> <li>▣ Minimal experiments needed to ensure proof of concept</li> <li>▣ Personnel with capabilities to file minimal regulatory requirements in limited regions</li> </ul>	<ul style="list-style-type: none"> <li>▣ \$\$</li> </ul>	<ul style="list-style-type: none"> <li>▣ 1-2 yrs + ongoing support</li> </ul>
<b>High complexity</b> (extensive/ambiguous regulatory and R&D pathways; many national regulatory approvals needed)	<ul style="list-style-type: none"> <li>▣ Ability to manage and respond to inquiries from an extensive network of clinical trial sites</li> <li>▣ Talent to analyze data and ensure efficacy of trials; to test for product safety and quality</li> <li>▣ Personnel with capabilities to complete and continuously respond to numerous regulatory filings in multiple regions</li> <li>▣ Relationships and working knowledge of multiple local regulators and requirements</li> <li>▣ Project management to ensure coordination across all functions</li> </ul>	<ul style="list-style-type: none"> <li>▣ \$\$\$\$</li> </ul>	<ul style="list-style-type: none"> <li>▣ 2-5 yrs + ongoing support</li> </ul>

<sup>1</sup> Time frame associated with a market leader, could take longer depending on internal expertise and capabilities; findings based on expert interviews. Resources and time frame are directional only (not intended to be precise).



# Worksheet: Capabilities and resources required to establish high-quality, cost-efficient manufacturing and supply chain

\$ = <\$10,000  
 \$\$ = \$10,000-\$100,000

\$\$\$ = \$100,000-\$1M  
 \$\$\$\$ = >\$1M

**Purpose:** Given product profile, understand capabilities and resources required to scale-up product, and which capabilities you are able to develop in-house

**Instruction:** For the product characteristic that better describes your innovation (those already mapped out in step 1A), select capabilities you already have in-house or would likely be able to organically develop

	Capabilities required	Resources required	Time frame <sup>1</sup>
<p><b>Low complexity</b>                      (simple process; easy to scale with a single manufacturer; many potential options)</p>	<ul style="list-style-type: none"> <li>▣ Ability to perform basic contracting and management of a single manufacturer</li> <li>▣ Minimal personnel time needed to monitor and control the quality of the manufacturing process</li> </ul>	<ul style="list-style-type: none"> <li>▣ \$</li> </ul>	<ul style="list-style-type: none"> <li>▣ 1-2 yrs + ongoing support</li> </ul>
<p><b>High complexity</b>                      (highly specialized manufacturing process; require multiple suppliers &amp; manufacturers; limited options)</p>	<ul style="list-style-type: none"> <li>▣ Ability to carry out extensive contracting and diligence to identify high quality, cost-effective manufacturers and suppliers</li> <li>▣ In-house staff to manage multiple manufacturers and suppliers, often across countries</li> <li>▣ Personnel with capabilities and expertise to monitor and control the quality of the technical manufacturing process</li> </ul>	<ul style="list-style-type: none"> <li>▣ \$\$</li> </ul>	<ul style="list-style-type: none"> <li>▣ 1-2 yrs + ongoing support</li> </ul>

<sup>1</sup> Time frame associated with a market leader, could take longer depending on internal expertise and capabilities; findings based on expert interviews. Resources and time frame are directional only (not intended to be precise).

# Worksheet: Capabilities and resources required to provide needed distribution and servicing

\$ = <\$10,000  
 \$\$ = \$10,000-\$100,000

\$\$\$ = \$100,000-\$1M  
 \$\$\$\$ = >\$1M

**Purpose:** Given product profile, understand capabilities and resources required to scale-up product, and which capabilities you are able to develop in-house

**Instruction:** For the product characteristic that better describes your innovation (those already mapped out in step 1A), select capabilities you already have in-house or would likely be able to organically develop

	Capabilities required	Resources required	Time frame <sup>1</sup>
<b>Low complexity</b> (no need for a distribution/logistics network; minimal requirements for servicing)	<ul style="list-style-type: none"> <li>▪ Simple distribution and logistics capabilities to bring product to buyers</li> <li>▪ Minimal to no servicing capabilities required</li> </ul>	<ul style="list-style-type: none"> <li>▪ \$-\$\$\$</li> </ul>	<ul style="list-style-type: none"> <li>▪ 1-2 yrs + ongoing support</li> </ul>
<b>High complexity</b> (need extensive distribution/logistics network; significant requirements for locally-based servicing)	<ul style="list-style-type: none"> <li>▪ Extensive and complex distribution channels to bring product to buyers / end users (could require last-mile distribution logistics)</li> <li>▪ Ability to manage inventory and order fulfillment across many buyers and intermediary distributors</li> <li>▪ Extensive in-person servicing capability</li> </ul>	<ul style="list-style-type: none"> <li>▪ \$\$\$</li> </ul>	<ul style="list-style-type: none"> <li>▪ 1-2 yrs + ongoing support</li> </ul>

<sup>1</sup> Time frame associated with a market leader, could take longer depending on internal expertise and capabilities; findings based on expert interviews. Resources and time frame are directional only (not intended to be precise).

# Worksheet: Summary of need for outside capabilities and resources to scale-up innovation

\$ = <\$10,000  
 \$\$ = \$10,000-\$100,000  
 \$\$\$ = \$100,000-\$1M  
 \$\$\$\$ = >\$1M  
 No need for outside capacity  
 Will rely entirely on outside capacity

**Purpose:** Summarize your needs to access capabilities and resources from outside parties for scale-up

**Instruction:** List out the unchecked capabilities from step 1B under "key capability gaps"; based on the gaps listed, color in the "moons" at the bottom of the worksheet to indicate degree of need for outside capacity

<p><b>Ensure user acceptance and generate demand; ensure adoption within policy</b></p>	<p><b>Acquire buyers and negotiate sales</b></p>	<p><b>Complete clinical trials and obtain regulatory approval</b></p>	<p><b>Establish high-quality, cost-efficient manufacturing</b></p>	<p><b>Provide needed distribution and servicing to buyers and/or users</b></p>
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*In each column, list out unchecked capabilities from prior worksheets*


**Key capability gaps**

Full moon = missing all capabilities required; 1/2 moon = missing 50% of capabilities required; empty moon = not missing any capabilities

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**Need for outside capabilities**

Copy required resource indicated in prior worksheets (\$-\$\$\$\$)

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**Aggregate funding required**

# BRILLIANCE AS AN EXAMPLE

## Worksheet: Product Profile Mapping

Product profile dimensions	Scaling activities impacted	Product characteristics	
<p><b>i</b> Degree of acceptance among users and other stakeholders</p>	<p>Ensure user acceptance and generate demand; ensure adoption within policy</p>	<p><input checked="" type="checkbox"/> <b>Low acceptance hurdle</b> (existing market with healthy user demand; minimal user education or behavioral change required; no need for policy change)</p>	<p><input type="checkbox"/> <b>High acceptance hurdle; aka “paradigm shift”</b> (limited existing demand; significant user education and behavioral changes required; need to change policies)</p>
<p><b>ii</b> Structure of buyer market (can select more than 1)</p>	<p>Acquire buyers and negotiate sales</p>	<p><input type="checkbox"/> <b>Very consolidated market of one or a few donor procurers</b></p> <p><input checked="" type="checkbox"/> <b>Consolidated market of large buyers</b> (often public or NGOs)</p>	<p><input checked="" type="checkbox"/> <b>Fragmented market of provider purchasers</b> (non-public and/or public)</p> <p><input type="checkbox"/> <b>Very fragmented market of individual consumers as buyers</b></p>
<p><b>iii</b> Complexity of clinical &amp; regulatory needs</p>	<p>Complete clinical trials and obtain regulatory approval</p>	<p><input checked="" type="checkbox"/> <b>Low complexity</b> (simple clinical/regulatory pathways; few regulatory approvals needed)</p>	<p><input type="checkbox"/> <b>High complexity</b> (extensive/ambiguous clinical/regulatory pathways; many national regulatory approvals needed)</p>
<p><b>iv</b> Complexity of manufacturing &amp; supply chain</p>	<p>Establish high-quality, cost-efficient manufacturing</p>	<p><input type="checkbox"/> <b>Low complexity</b> (simple manufacturing process; easy to scale with a single manufacturer; many potential options)</p>	<p><input checked="" type="checkbox"/> <b>High complexity</b> (highly specialized manufacturing process; require multiple sup-pliers &amp; manufacturers; limited options)</p>
<p><b>v</b> Complexity of distribution &amp; servicing</p>	<p>Provide needed distribution and servicing to buyers and/or users</p>	<p><input type="checkbox"/> <b>Low complexity</b> (no need for a distribution/logistics network; minimal requirements for servicing)</p>	<p><input checked="" type="checkbox"/> <b>High complexity</b> (need extensive distribution/logistics network; significant requirements for locally-based servicing)</p>

To assess capabilities and resources most needed for scale-up, innovators can first map their products along these 5 dimensions that matter most to the scale-up process

# Worksheet: Capabilities and resources required to ensure user acceptance and policy adoption

\$ = <\$10,000  
 \$\$ = \$10,000-\$100,000  
 \$\$\$ = \$100,000-\$1M  
 \$\$\$\$ = >\$1M  
 ✓ Capabilities Brilliance has/could develop internally

	Capabilities required	Resources required	Time frame <sup>1</sup>
<b>Low acceptance hurdle</b> (existing market with healthy user demand; minimal user education or behavioral change required; no need for policy change)	<ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Minimal to no end user training/ education capacity required</li> <li><input type="checkbox"/> Minimal to no capabilities required to effect policy/guideline changes for adoption of innovation</li> <li><input checked="" type="checkbox"/> Minimal long term adjustment of messaging of value proposition</li> </ul>	<ul style="list-style-type: none"> <li>▪ \$-\$\$</li> </ul>	<ul style="list-style-type: none"> <li>▪ &lt;1 yr</li> </ul>
<b>High acceptance hurdle; aka “paradigm shift”</b> (limited existing demand; significant user education and behavioral changes required; need to change policies)	<ul style="list-style-type: none"> <li><input type="checkbox"/> Ability to generate and tailor relevant efficacy data and messages to stakeholders and key influencers</li> <li><input type="checkbox"/> Capabilities to train end users</li> <li><input type="checkbox"/> Ability and channels to effectively convey messaging and value proposition tailored to end user groups</li> <li><input type="checkbox"/> Ongoing capacity to monitor and adjust product and messaging</li> </ul>	<ul style="list-style-type: none"> <li>▪ \$\$\$-\$\$\$\$</li> </ul>	<ul style="list-style-type: none"> <li>▪ &gt; 1 yr + ongoing support</li> </ul>

**D-Rev had strong capabilities to gain acceptance among users, buyers, and stakeholders for Brilliance**

<sup>1</sup> Time frame associated with a market leader, could take longer depending on internal expertise and capabilities; findings based on expert interviews. Resources and time frame are directional only (not intended to be precise).







# Worksheet: Capabilities and resources required to acquire buyers and negotiate sales

\$ = <\$10,000  
 \$\$ = \$10,000-\$100,000  
 \$\$\$ = \$100,000-\$1M  
 \$\$\$\$ = >\$1M

✓ Capabilities Brilliance has/could develop internally

	Capabilities required	Resources required	Time frame <sup>1</sup>
Very consolidated market of one or a few donor procurers	<ul style="list-style-type: none"> <li>Ability to negotiate with single or few stakeholders</li> <li>Deep knowledge of procurement processes</li> </ul>	<ul style="list-style-type: none"> <li>\$-\$</li> </ul>	<ul style="list-style-type: none"> <li>1 yr</li> </ul>
Consolidated market of large buyers (often public or NGOs)	<ul style="list-style-type: none"> <li>Capabilities and personnel to address buying needs of multiple governments and large provider networks</li> <li>Personnel to navigate contracts (tenders) with several stakeholders</li> <li>Limited sales force to address small number of buyers</li> </ul>	<ul style="list-style-type: none"> <li>\$\$-\$\$\$</li> </ul>	<ul style="list-style-type: none"> <li>1 yr</li> </ul>
Fragmented market of provider purchasers (non-public and/or public)	<ul style="list-style-type: none"> <li>Capabilities and personnel to address buying needs and contracts with a large number of diverse stakeholders</li> <li>Path and skills to create a recognizable and trusted brand</li> <li>Moderate size sales force to address numerous buyers</li> </ul>	<ul style="list-style-type: none"> <li>\$\$-\$\$\$</li> </ul>	<ul style="list-style-type: none"> <li>1 yr</li> </ul>
Very fragmented market of individual consumers as buyers	<ul style="list-style-type: none"> <li>Path and skills to create a recognizable trusted brand</li> <li>Ability to create and implement consumer advertising and marketing campaigns</li> <li>Potential need for a large size sales force</li> </ul>	<ul style="list-style-type: none"> <li>\$\$\$\$</li> </ul>	<ul style="list-style-type: none"> <li>1 yr</li> </ul>

**D-Rev had limited capabilities to reach and acquire buyers**

<sup>1</sup> Time frame associated with a market leader, could take longer depending on internal expertise and capabilities; findings based on expert interviews. Resources and time frame are directional only (not intended to be precise).

# Worksheet: Capabilities and resources required to complete clinical trials and obtain regulatory approval

\$ = <\$10,000  
 \$\$ = \$10,000-\$100,000  
 \$\$\$ = \$100,000-\$1M  
 \$\$\$\$ = >\$1M  
 ✓ Capabilities Brilliance has/could develop internally

	Capabilities required	Resources required	Time frame <sup>1</sup>
<b>Low complexity</b> (simple/established regulatory and R&D pathways; few regulatory approvals needed)	<ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Minimal experiments needed to ensure proof of concept</li> <li><input type="checkbox"/> Personnel with capabilities to file minimal regulatory requirements in limited regions</li> </ul>	<ul style="list-style-type: none"> <li>▪ \$\$</li> </ul>	<ul style="list-style-type: none"> <li>▪ 1-2 yrs + ongoing support</li> </ul>
<b>High complexity</b> (extensive/ambiguous regulatory and R&D pathways; many national regulatory approvals needed)	<ul style="list-style-type: none"> <li><input type="checkbox"/> Ability to manage and respond to inquiries from an extensive network of clinical trial sites</li> <li><input type="checkbox"/> Talent to analyze data and ensure efficacy of trials; to test for product safety and quality</li> <li><input type="checkbox"/> Personnel with capabilities to complete and continuously respond to numerous regulatory filings in multiple regions</li> <li><input type="checkbox"/> Relationships and working knowledge of multiple local regulators and requirements</li> <li><input type="checkbox"/> Project management to ensure coordination across all functions</li> </ul>	<ul style="list-style-type: none"> <li>▪ \$\$\$\$</li> </ul>	<ul style="list-style-type: none"> <li>▪ 2-5 yrs + ongoing support</li> </ul>
<b>D-Rev had no capabilities to navigate the regulatory and R&amp;D requirements for Brilliance</b>			

<sup>1</sup> Time frame associated with a market leader, could take longer depending on internal expertise and capabilities; findings based on expert interviews. Resources and time frame are directional only (not intended to be precise).





# Worksheet: Capabilities and resources required to establish high-quality, cost-efficient manufacturing and supply chain

\$ = <\$10,000  
\$\$ = \$10,000-\$100,000

\$\$\$ = \$100,000-\$1M  
\$\$\$\$ = >\$1M

✓ Capabilities Brilliance has/could develop internally

	Resources required	Time frame <sup>1</sup>
<p><b>Low complexity</b> (simple process; easy to scale with a single manufacturer; many potential options)</p> <ul style="list-style-type: none"> <li>Ability to perform basic contracting and management of a single manufacturer</li> <li>Minimal personnel time needed to monitor and control the quality of the manufacturing process</li> </ul>	\$	1-2 yrs + ongoing support
<p><b>High complexity</b> (highly specialized manufacturing process; require multiple suppliers &amp; manufacturers; limited options)</p> <ul style="list-style-type: none"> <li>Ability to carry out extensive contracting and diligence to identify high quality, cost-effective manufacturers and suppliers</li> <li>In-house staff to manage multiple manufacturers and suppliers, often across countries</li> <li>Personnel with capabilities and expertise to monitor and control the quality of the technical manufacturing process</li> </ul>	\$\$	1-2 yrs + ongoing support

**D-Rev had limited capabilities to reach and acquire buyers**

<sup>1</sup> Time frame associated with a market leader, could take longer depending on internal expertise and capabilities; findings based on expert interviews. Resources and time frame are directional only (not intended to be precise).

# Check list: Capabilities and resources required to provide needed distribution and servicing

\$ = <\$10,000  
 \$\$ = \$10,000-\$100,000  
 \$\$\$ = \$100,000-\$1M  
 \$\$\$\$ = >\$1M  
 ✓ Capabilities Brilliance has/could develop internally

	Capabilities required	Resources required	Time frame <sup>1</sup>
<b>Low complexity</b> (no need for a distribution/logistics network; minimal requirements for servicing)	<ul style="list-style-type: none"> <li>▪ Simple distribution and logistics capabilities to bring product to buyers</li> <li>▪ Minimal to no servicing capabilities required</li> </ul>	<ul style="list-style-type: none"> <li>▪ \$-\$\$\$</li> </ul>	<ul style="list-style-type: none"> <li>▪ 1-2 yrs + ongoing support</li> </ul>
<b>High complexity</b> (need extensive distribution/logistics network; significant requirements for locally-based servicing)	<ul style="list-style-type: none"> <li>▪ Extensive and complex distribution channels to bring product to buyers / end users (could require last-mile distribution logistics)</li> <li>▪ Ability to manage inventory and order fulfillment across many buyers and intermediary distributors</li> <li>▪ Extensive in-person servicing capability</li> </ul>	<ul style="list-style-type: none"> <li>▪ \$\$\$</li> </ul>	<ul style="list-style-type: none"> <li>▪ 1-2 yrs + ongoing support</li> </ul>

**D-Rev had no capabilities to manage distribution and servicing for Brilliance**

<sup>1</sup> Time frame associated with a market leader, could take longer depending on internal expertise and capabilities; findings based on expert interviews. Resources and time frame are directional only (not intended to be precise).

# Worksheet: Summary of need for outside capabilities and resources to scale-up innovation

= <\$10,000  
 = \$10,000-\$100,000  
 = \$100,000-\$1M  
 = >\$1M  
 No need for outside capacity  
 Will rely entirely on outside capacity

Ensure user acceptance and generate demand; ensure adoption within policy

Acquire buyers and negotiate sales

Complete clinical trials and obtain regulatory approval

Establish high-quality, cost-efficient manufacturing and/or users

Provide needed distribution and servicing to buyers and/or users

In each column, list out unchecked capabilities from prior worksheets

## Key capability gaps

- Some capabilities required to effect policy/guideline changes for adoption of innovation, given Brilliance uses LED instead of CFLs

- Capabilities and personnel to address buying needs of multiple governments and large provider networks
- Personnel to navigate contracts (tenders) with several stakeholders
- Sales force to address small/moderate number of buyers
- Capabilities and personnel to address buying needs and contracts with a large number of diverse stakeholders
- Path and skills to create a recognizable and trusted brand

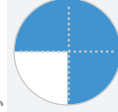
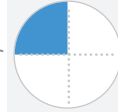
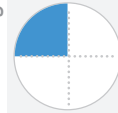
- Personnel with capabilities to file minimal regulatory requirements in limited regions

- In house staff to manage multiple manufacturers and suppliers, often across countries
- Personnel with capabilities and expertise to monitor and QC technical manufacturing process

- Extensive and complex distribution channels to bring product to buyers / end users (could require last-mile distribution logistics)
- Ability to manage inventory and order fulfillment across many buyers and intermediary distributors
- Extensive in-person servicing capability

Full moon = missing all capabilities required; 1/2 moon = missing 50% of capabilities required; empty moon = not missing any capabilities

## Need for outside capabilities



## Aggregate funding required

\$

\$\$\$

\$

\$\$

\$\$\$

Copy required resource indicated in prior worksheets (\$-\$\$\$)



## EXERCISE 2: SELECT APPROPRIATE SCALING MODEL(S)

The choice of scaling model(s) is determined by the answers to two questions: "Which model is feasible for me to pursue?" and "Which model is best aligned with my goals and preferences?" We designed this exercise to help innovators answer these two questions and identify the best-suited scaling model. As previously noted, this exercise should be revisited periodically as the determinants for either feasibility or preference may change along the innovator's journey.

This exercise also has three sequential components:

**A**

### Assessing the feasibility of pursuing and implementing each scaling model

For each of the five models, the innovator is asked to rate the likelihood that their organization could execute the requirements introduced on page 6 of the guide successfully. Innovators and advisors who have successfully scaled innovations say this is a critical step. Many have noted that understanding how feasible a particular model was for their organization and product helped them narrow down the model choices for scale, and helped them identify what they needed to pursue a particular model type.

**B**

### Assessing the preferences for each scaling model

The innovator should clearly define their goals and preferences and those of their organization, and rate their preference for each of the five models. The innovator must truly understand if a particular model aligns with these preferences. For example, as noted in the D-Rev Brilliance case study, the innovators wished to focus the organization on creating innovative new products, rather than build the capabilities to scale-up a product. Understanding this preference helped D-Rev choose licensing over other model types.

**C**

### Prioritizing scale-up models

Using the ratings from Parts A and B of this exercise, the innovator can plot the five scaling models on a matrix with feasibility and preference as the two axes. D-Rev Brilliance's prioritization of the five scaling models is shown below. The model emerging on the top right quadrant is the "best fit" - for Brilliance, it was licensing out. If the top right quadrant is empty, the innovator should consider the most feasible models in the top left quadrant, even though they have a low preference rating. If these models are unappealing, the innovator should then decide whether to continue pursuing the innovation or to terminate or divest it.



# Worksheet: Assessment of feasibility for innovator to pursue each scaling model given requirements

- Requirement has >50% likelihood to be met
- Requirement can be met

**Model feasibility** Summarize (using high/medium/low) the likelihood for the requirements of each scaling model to be met, i.e., feasibility

**Requirements to make model feasible** Shade circles to assess likelihood for requirements to be met. (½ = >50% likelihood to be met; Full = Requirement can be met)

Scaling model	Requirements to make model feasible	Model feasibility
<b>1</b>  Organic growth with selective out-sourcing	<ul style="list-style-type: none"> <li><input type="checkbox"/> Relatively few capability gaps to be filled (identified in Exercise 1)</li> <li><input type="checkbox"/> Partners exist in the target market that can address capability gaps</li> <li><input type="checkbox"/> Existence of long-term funding sources required to scale and ability to fundraise</li> </ul>	
<b>2</b>  Multi-stakeholder partnership	<ul style="list-style-type: none"> <li><input type="checkbox"/> Innovation has clear value proposition and potential to be of extremely high impact in target population</li> <li><input type="checkbox"/> Partner(s) with shared goals exist in the target markets to form multi-stakeholder partnership</li> <li><input type="checkbox"/> Some in-house scale-up capabilities to contribute in the partnership</li> <li><input type="checkbox"/> Some evidence of compelling commercial value</li> </ul>	
<b>3</b>  Licensing out	<ul style="list-style-type: none"> <li><input type="checkbox"/> Can demonstrate clear and compelling commercial value</li> <li><input type="checkbox"/> Licensees likely to exist in the target market</li> <li><input type="checkbox"/> Existence of funding sources and ability to fundraise amount required to reach licensing milestone</li> </ul>	
<b>4</b>  Open licensing	<ul style="list-style-type: none"> <li><input type="checkbox"/> IP is valuable (commercial value and/or social value) and transferable to others in the market</li> <li><input type="checkbox"/> Potential replicators likely exist in the market</li> </ul>	
<b>5</b>  Getting acquired	<ul style="list-style-type: none"> <li><input type="checkbox"/> Can demonstrate clear and compelling commercial value</li> <li><input type="checkbox"/> Acquirers likely to exist in the target market</li> <li><input type="checkbox"/> Existence of funding sources and ability to fundraise amount required to reach acquisition milestone</li> </ul>	

Based on number of requirements filled and not filled for each model, innovators can eliminate some scaling models from consideration



# Worksheet: Assessment of innovator's preference to pursue each scaling model

**Overall preference rating** Your responses to the reflection questions and reference implications of each scaling model (next slide) to rate your overall preference for each model (using high/medium/low)

**Responses** Answer these core questions to inform your preferences for each scaling model

**Suggested questions to reflect on preferences**

<b>Ownership</b>	<ul style="list-style-type: none"> <li>Do I want to maintain full legal ownership of my product?</li> </ul>	
<b>Control</b>	<ul style="list-style-type: none"> <li>How much do I want to control / have decision rights over the future direction of this product?</li> <li>Do I want to be the CEO of a business?</li> <li>Do I want to see my product through launch and scale-up?</li> </ul>	
<b>Financial reward</b>	<ul style="list-style-type: none"> <li>How much do I want to maximize financial rewards?</li> </ul>	
<b>Risk</b>	<ul style="list-style-type: none"> <li>What is my appetite for risk?</li> </ul>	
<b>Time/capacity</b>	<ul style="list-style-type: none"> <li>Do I want to free up time and capacity to pursue other projects?</li> </ul>	

<b>1</b> Organic growth with selective out-sourcing	
<b>2</b> Multi-stakeholder partnership	
<b>3</b> Licensing out	
<b>4</b> Open licensing	
<b>5</b> Getting acquired	

## Implications for innovators to pursue each scaling model

	High Degree	Low Degree	Legal ownership	Decision making power/control	Potential financial upside	Ability to “off load” risk	Ability to free up time and capacity
<p><b>Organic growth with selective out-sourcing</b> 1</p>							
<p><b>Multi-stakeholder partnership</b> 2</p>							
<p><b>Licensing out</b> 3</p>							
<p><b>Open licensing</b> 4</p>							
<p><b>Getting acquired</b> 5</p>							

**Variable:** depends on the dynamics between profit margin (likely lower) and the volume (likely larger)

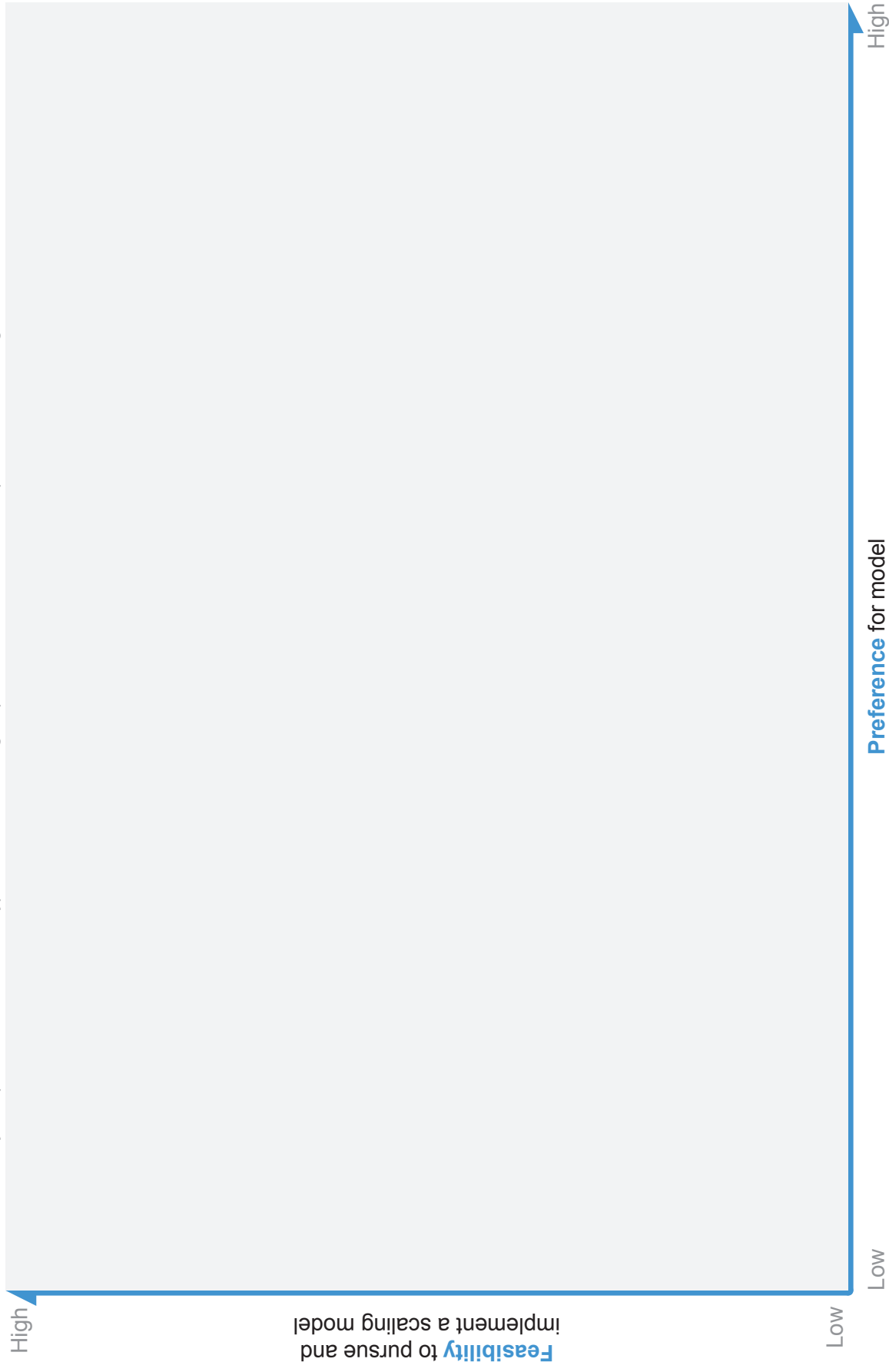
**Variable:** depends on the contractual terms and the licensee’s ability to commercialize the product

**Variable:** depends on the willingness of the innovator to support others in adopting the technology

**Variable:** depends on the valuation and deal terms

# Worksheet: Prioritization of scaling models based on feasibility and preference




Based on feasibility and preference for model types identified during step A and B of this exercise, plot the five scaling models on this matrix



# BRILLIANCE AS AN EXAMPLE

# Worksheet: Assessment of feasibility for innovator to pursue each scaling model given requirements

- Requirement has >50% likelihood to be met
- Requirement can be met

Scaling model	Requirements to make model feasible	Model feasibility
<b>1</b>  Organic growth with selective out-sourcing	<ul style="list-style-type: none"> <li><input type="radio"/> Relatively few capability gaps to be filled (identified in Exercise 1)</li> <li><input type="radio"/> Partners exist in the target market that can address capability gaps</li> <li><input type="radio"/> Existence of long-term funding sources required to scale and ability to fundraise</li> </ul>	<div style="border: 1px solid gray; padding: 10px; width: 100px; margin: 0 auto;">LOW</div>
<b>2</b>  Multi-stakeholder partnership	<ul style="list-style-type: none"> <li><input type="radio"/> Innovation has clear value proposition and potential to be of extremely high impact in target population</li> <li><input type="radio"/> Partner(s) with shared goals exist in the target markets to form multi-stakeholder partnership</li> <li><input type="radio"/> Some in-house scale-up capabilities to contribute in the partnership</li> <li><input type="radio"/> Some evidence of compelling commercial value</li> </ul>	<div style="border: 1px solid gray; padding: 10px; width: 100px; margin: 0 auto;">Medium/low</div>
<b>3</b>  Licensing out	<ul style="list-style-type: none"> <li><input type="radio"/> Can demonstrate clear and compelling commercial value</li> <li><input type="radio"/> Licensees likely to exist in the target market</li> <li><input type="radio"/> Existence of funding sources and ability to fundraise amount required to reach licensing milestone</li> </ul>	<div style="border: 1px solid gray; padding: 10px; width: 100px; margin: 0 auto;">High/medium</div>
<b>4</b>  Open licensing	<ul style="list-style-type: none"> <li><input type="radio"/> IP is valuable (commercial value and/or social value) and transferable to others in the market</li> <li><input type="radio"/> Potential replicators likely exist in the market</li> </ul>	<div style="border: 1px solid gray; padding: 10px; width: 100px; margin: 0 auto;">LOW</div>
<b>5</b>  Getting acquired	<ul style="list-style-type: none"> <li><input type="radio"/> Can demonstrate clear and compelling commercial value</li> <li><input type="radio"/> Acquirers likely to exist in the target market</li> <li><input type="radio"/> Existence of funding sources and ability to fundraise amount required to reach acquisition milestone</li> </ul>	<div style="border: 1px solid gray; padding: 10px; width: 100px; margin: 0 auto;">Medium/low</div>

1 Time frame associated with a market test used to reach acquisition milestone. Resources and time frame are directional only (not intended to be precise); findings based on expert interviews.



# Worksheet: Assessment of innovator's preference to pursue each scaling model

Suggested questions to reflect on preferences

Responses

<b>Ownership</b>	<ul style="list-style-type: none"> <li>Do I want to maintain full legal ownership of my product?</li> </ul>	<ul style="list-style-type: none"> <li>Strong preference for legal ownership over IP to retain ability to course correct</li> </ul>
<b>Control</b>	<ul style="list-style-type: none"> <li>How much do I want to control / have decision rights over the future direction of this product?</li> <li>Do I want to be the CEO of a business?</li> <li>Do I want to see my product through launch and scale-up?</li> </ul>	<ul style="list-style-type: none"> <li>Need enough control to ensure product is reaching those most in need; comfortable with someone external driving scale-up otherwise</li> </ul>
<b>Financial reward</b>	<ul style="list-style-type: none"> <li>How much do I want to maximize financial rewards?</li> </ul>	<ul style="list-style-type: none"> <li>Not primary driver, but would like to refuel company</li> </ul>
<b>Risk</b>	<ul style="list-style-type: none"> <li>What is my appetite for risk?</li> </ul>	<ul style="list-style-type: none"> <li>Moderate</li> </ul>
<b>Time/capacity</b>	<ul style="list-style-type: none"> <li>Do I want to free up time and capacity to pursue other projects?</li> </ul>	<ul style="list-style-type: none"> <li>Want to free up resources to develop new products</li> </ul>

Overall preference rating

<b>1</b> Organic growth with selective out-sourcing	Low/medium
<b>2</b> Multi-stakeholder partnership	Medium
<b>3</b> Licensing out	High/medium
<b>4</b> Open licensing	Low
<b>5</b> Getting acquired	Low

## Worksheet: Prioritization of scaling models based on feasibility and preference



<sup>1</sup> Time frame associated with a market leader, could take longer depending on internal expertise and capabilities, findings based on expert interviews. Resources and time frame are directional only (not intended to be precise).





## EXERCISE 3: UNDERSTANDING THE KEY CONSIDERATIONS FOR THE CHOSEN SCALING MODEL(S)

Having a sense for which scaling model might be a good fit is akin to knowing the general direction of a journey. There is much to be done to sketch out and pursue a successful pathway to scale. An innovator needs to understand the important decision points, necessary milestones, and preferred timing along the journey. To help him or her do so, in this exercise, we present the most critical questions that an innovator must be able to answer when choosing a scaling model. For each scaling model, the questions fall into five categories:



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What do I need the outside party to bring?



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Which organizations are likely to meet my needs?



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What values do I need to demonstrate to them?



---

What timing should I aim for?



---

What types of capital would I need, how much, and when?

Many of the questions require fact-gathering, analysis, reaching out to potential partners, and pressure-testing with mentors. If the innovation is still at a very early stage, the answers to some questions may not yet be available. Therefore, it may not be possible or practical to complete this exercise in one afternoon. Instead, we offer these questions as tools to help innovators structure their thought-process and prioritize activities as they chart a pathway to scale. To help innovators answer these questions, we have highlighted a few key considerations that stood out from our research and interviews while preparing this guide.

# SCALING MODEL 1: ORGANIC GROWTH WITH SELECTIVE OUT-SOURCING



## What do I need in a partner?

Which capability gaps must the partner be able to fill?

What other characteristics should an ideal partner have? E.g.:

- Size, maturity
- Brand and reputation
- Footprint in target geographies
- Experience with similar products and markets
- Ability to grow with me through the scaling process
- Relationships with key stakeholders
- Network and/or the ability to attract capital

What values does the partner need to have? Signs of value alignment:

- Vision of success for my product
- A customer base that aligns with my target users
- A willingness to let me influence strategy



## Which partners are most likely to meet my needs?

Which types of organizations are best equipped to fill each of my capability gaps?

How do I create a short list of organizations that I should consider partnering with?

Which organizations on this list are most aligned with my criteria?



## What value do I need to show potential partners?

Which of my preferred potential partners are interested in working with me? What motivates them? E.g.:

- Compelling social and/or commercial value
- Strategic alignment with existing markets
- Compatibility with existing product / project portfolio
- User demand / existence of market
- Commercial sustainability and attractiveness (might not be needed)

What do I need to demonstrate to attract them? E.g.:

- Technical viability (through proof of concept or pilot trials)
- Potential impact
- Strategic relevance to the partner, in terms of geographies, health issues, target markets, etc.

What milestones must I reach to demonstrate success in these areas?

Do I need to make changes to my current legal structure (e.g. start a new entity that owns the IP) to reach these milestones?



## What timing should I aim for?

Are there benefits to partnering early vs late for each area of partnership? Considerations include:

- Influence on other decisions (e.g. engaging a manufacturer early could affect product design)
- Potential financial return
- Bargaining power in contract negotiations
- Amount of time and resources I am willing to spend to reach each milestone



## What types of funding do I need and when?

How much additional funding do I need at each stage to drive the scale-up of my product?

Given the stages at which I need funding, which types of capital should I seek?

- Friends and family money
- Competition and prize money
- Grants
- Program-related investments
- Impact capital
- Angel equity
- Equity investor
- Debt investor
- Revenue-based financing
- Convertible debt

What terms and restrictions would each type of capital entail?

- IP openness
- Growth strategy
- Payment timeline and schedule, interest rate (for debt)
- Valuation, voting rights (for equity)

**Don't forget about value alignment:** In defining the traits of an ideal partner and vetting potential candidates, it is important to confirm that their values are in alignment with yours, in addition to their capabilities and track record. Global health innovators are often driven by the pursuit of social impact, instead of, or in addition to, financial return. The population they wish to target and the price-point of their products are not usually financially optimal. Innovators cannot assume that potential partners will share these impact-driven goals. For example, the most profitable strategy for distributors and resellers could be selling to more affluent customer segments, at the expense of reaching those most in need. Doing thorough due diligence on the values of potential partners is, therefore, critical for ensuring the integrity of the product's intended impact and preserving the longevity of the partnership.

**Understand what potential partners need from you:** A healthy partnership is built on the foundation of trust, understanding, and mutual benefit. While it might be relatively straightforward for innovators to identify what they need from partners, it is much more difficult to know what their counterparts value. We encourage innovators to identify and begin engaging with potential partners early on. Understanding precisely what partners require could imply a change in strategic direction or product design, even in the early stages of an innovation.

***Anecdote:** The inventors of an Augmented Infant Resuscitator (AIR) from Mbarara University, Uganda and Boston realized early on that partnership with local distributors would be vital for taking their product to market and to scale. At the advice of their mentors, who understood medical devices, they learned that distributors in East Africa require products to be at a certain price-point to fit into their portfolios. The team asked market experts to explain the price-points needed to make their products marketable, and worked with manufacturers to gain an understanding of unit economics. By evaluating both end-user and distributor preferences and inputs, the AIR team was able to work with manufacturers to bring the Cost of Goods down to a level that permitted performance at a price-point that would facilitate scale in the intended target settings. Without an early understanding of future distribution partners' needs, the innovators would have gone too far down the product development path (e.g., manufacturing processes and equipment locked in and costly to change) to easily course-correct.*

Typical things that partners look for could include:

- **Evidence of technical viability:** Unless you are simply paying for a contractor's services, most partners want to see proof of concept or pilot trials that demonstrate the technical viability of the innovation. As proof of concept can mean many things, it is important to talk to partners directly and ask them what they are looking for.
- **Evidence of impact:** NGO and mission-driven partners are likely to look for evidence of social impact. It is important to understand the degree of robustness in the evidence required by potential partners (e.g., clinical trials or field testing, results specific to certain geographies and/or user segments, sample size, confidence interval of the results, etc.).
- **Strategic relevance:** Socially-driven organizations usually have clear priorities across geographies, health issues, and user segments. Being able to relate the innovation to their specific areas of interest would make the partnership more feasible. Similarly, commercially-minded partners will seek strategic alignment between the innovation and their own businesses, whether it is to better serve their existing customers or to grow into a new market.
- **Commercial sustainability:** Partners with a vested interest in the long-term sustainability of a product require evidence of its commercial viability, including proven demand from end-users, the existence of buyers that are willing and able to pay, plausible revenue streams and/or other sources of capital. Again, it is important to understand how potential partners define commercial viability. Depending on their motivations, some might only require the ability to recover costs, while others look for a certain level of profitability.

# SCALING MODEL 2: MULTI-STAKEHOLDER PARTNERSHIP



## What do I need from a multi-stakeholder partnership?

Which capability gaps must the group of partners be able to fill?

What roles do the multi-stakeholder partners need to perform?

How much decision-making control do I want to maintain in the multi-stakeholder partnership?

What other characteristics would an ideal set of partners have? E.g.:

- Size, maturity
- Brand and reputation
- Footprint in target geographies
- Experience with similar products and markets
- Ability to grow with me through the scaling process
- Relationships with key stakeholders
- Capital or the ability to attract capital

What values do the partners need to have? Signs of value alignment:

- Vision of success for my product
- A customer base that aligns with my target users
- The willingness to let me influence strategy



## Which partners likely meet my needs?

Which types of organizations would likely meet my needs?

- Alliances/coalitions/public-private partnerships on a related issue
- Donors
- Governments
- Implementing NGOs
- Corporations

How should I develop a short list of specific organizations I should consider partnering with? What roles should they take on?

Which organizations from this list are most aligned with my criteria?



## What value do I need to show potential partners?

Which of my preferred partners are interested in working with me? What motivates them? E.g.:

- Compelling social value
- Need for multi-stakeholder partnership to address barriers that a single entity cannot

What do I need to demonstrate to attract them? E.g.:

- Technical viability (through proof of concept or pilot trials)
- Potential Impact
- Strategic relevance to the partner, in terms of geographies, health issues, target markets, etc.
- User demand / existence of market
- Commercial sustainability and attractiveness (might not be needed)

What milestones do I need to reach to demonstrate evidence in these areas?

Do I need to make changes to my current legal structure (e.g. start a new entity that owns the IP) to reach these milestones?



## What timing should I aim for?

Are there benefits to entering into a partnership early vs late? Considerations include:

- Influence on other decisions (e.g. engaging a manufacturer early could affect product design)
- Level of decision-making power in the partnership



## What types of funding do I need and when?

How much additional funding do I need to raise to reach the milestones required to enter into a multi-stakeholder partnership?

How much more funding would I need to raise after a multi-stakeholder partnership?

Given the stages at which I need funding, what are the potential types of capital?

- Friends and family money
- Competition and prize money
- Grants
- Program related investments
- Impact capital
- Angel equity
- Equity investor
- Debt investor
- Revenue-based financing
- Convertible debt

What terms and restrictions would each type of capital come with?

- IP openness
- Growth strategy
- Payment timeline and schedule, interest rate (for debt)
- Valuation, voting rights (for equity)

**Look in unlikely places to “seed” a multi-stakeholder partnership:** A multi-stakeholder partnership brings together the group of stakeholders required to address scale-up challenges that a single organization cannot do alone, often at the system-level. Sometimes, such a body already exists to help scale-up life-saving, health-promoting products. For example, today, a clean cookstove innovator would work with the Global Alliance for Clean Cookstoves to develop their business and scale-up. However, more often, a multi-stakeholder partnership is not readily found.

Innovators need to search for a partner with a shared interest and ability to galvanize other stakeholders to “seed” the multi-stakeholder partnership. This could include international agencies, donors, and large NGOs, as well as the less usual entities, such as governments at the national or sub-national level, academic institutions, physician alliances, and consumer groups.

**Anecdote:** In 2014, Medtronic sought to address the need for better management of traumatic brain injury in India but lacked any entry points to intervene on its own. It found a partner in the American Association of Physicians of Indian Origin. Together, they formed a public-private partnership model with the Indian state and central government to develop and implement national guidelines for managing traumatic brain injury patients.

**Be clear on the role of project manager:** In “Idea to Impact”, we introduced the concept of an “uptake coordinator”, also commonly referred to as a project manager. This role is vested with the responsibilities to convene stakeholders, delegate and coordinate work across them, share information, troubleshoot issues that arise, maintain a project timeline, and help prioritize decisions and activities. Such a role is integral to scaling up any innovation, and especially important to those being scaled up through a collaborative model involving multiple actors. The group of partners working together must clarify who is responsible for project management, or if a formal body should be created to serve that purpose. The designated project manager must be granted authority to lead, make decisions and hold all parties accountable. In exploring the model of scaling through a multi-stakeholder arrangement, we encourage innovators to raise these questions as early as possible with prospective partners. For more details on the concept of an “uptake coordinator”, including case studies and lessons learned, please refer to page 59 of “Idea to Impact”.



# SCALING MODEL 3: LICENSING OUT



## What do I need in a licensee?

Which capability gaps must the licensee be able to fill?

How much decision making control do I want to retain, if any?

What other characteristics would an ideal licensee have? E.g.:

- Size, maturity
- Brand and reputation
- Financial health and available capital
- Footprint in target geographies
- Product portfolio
- Relationships with key stakeholders

What values does the licensee need to have? Signs of value alignment:

- Vision of success for my product
- A customer base that aligns with my target users
- The willingness to let me influence strategy

How do I want the licensee to use and not to use my IP? Common restrictions to state in a license:

- Degree of exclusivity
- Components of the technology
- Geography
- "Field of use", or use cases
- Pricing
- Rights over modifications or derivatives



## Which licensees likely meet my needs?

What types of licensees would likely meet my needs? E.g.:

- Multi-national corporations
- Local manufacturers / distributors
- Innovation, R&D, design entities
- Global health organizations (e.g., PATH)

How do I create a short list of organizations I should consider as licensees?

Which organizations on the list are most aligned with my criteria?



## What value do I need to show potential licensees?

Which of my preferred licensees are interested in working with me? What motivates them? E.g.:

- Compelling commercial value
- Strategic alignment with existing markets / customer base
- Compatibility with existing product portfolio

What do I need to demonstrate to potential licensees? E.g.:

- Technical viability (through proof of concept or pilot trials)
- Potential impact
- Strategic relevance to the licensee, in terms of geographies, health issues, target markets, etc.
- User demand / existence of market
- Commercial sustainability and attractiveness
- Pathway to regulatory approval
- Manufacturability

What milestones do I need to reach to demonstrate evidence in these areas?

Do I need to make changes to my current legal structure (e.g. start a new entity that owns the IP) to reach these milestones?



## What timing should I aim for?

Are there benefits to licensing early vs late? Considerations include:

- The freedom to explore other scaling models
- Potential financial return
- Bargaining power in the license negotiations
- Amount of time and resources I am willing to spend to reach each milestone



## What types of funding do I need and when?

How much additional funding do I need to raise to reach the milestone required for licensing?

How much more funding would I need to raise after a licensing deal, if any?

Given the stages at which I need funding, what sources of capital might I pursue?

- Friends and family money
- Competition and prize money
- Grants
- Program-related investments
- Impact capital
- Angel equity
- Equity investor
- Debt investor
- Revenue-based financing
- Convertible debt

What terms and restrictions would each type of capital come with?

- IP openness
- Growth strategy
- Payment timeline and schedule, interest rate (for debt)
- Valuation, voting rights (for equity)

**Maximize your optionality:** A license is a document granting permission for another entity (the "licensee") to use a technology in exchange for a payment to the owner (the "licenser"). It is possible for a license to contain any number of restrictions on how the technology can be used, including exclusive permission, geographic scope, field of use (i.e., use case), ability to make alterations and more. Depending on the goals of the innovator, it could be limiting to license out all rights to one partner exclusively. If the goal is to ensure that the innovation reaches the greatest number of target beneficiaries, an innovator might only license out rights to sell to market segments that the licensee is best-suited to serve, and retain the option of working with other partners in other markets. If the goal is to address many use-cases through the technology, an innovator might want to limit the field of use in the licensing agreement so he or she is free to develop alternate use cases (e.g., apply the technology to another therapeutic area) later on. When in doubt, negotiate the narrowest set of permissions for which the licensee can use the technology.

**Use contract terms to achieve desired alignment with the licensee:** The earlier discussion on ensuring value-alignment (page 41) is equally important to innovators seeking licensing partners. By structuring the licensing agreement, innovators can influence licensees to pursue strategies aligned with their values, using measures such as differentiating the levels of licensing fees or royalties, fixing the price range. For example, in their licensing agreement with Phoenix Medical Systems, D-Rev set a lower royalty for each unit of Brilliance sold to public and district hospitals to incentivize sales to institutions serving communities with the most unmet need. The licensing agreement also contained a price cap that Brilliance set to ensure intended users could afford the product. We encourage innovators considering licensing out to learn from others who have successfully licensed, and to seek guidance from legal experts working in their field (e.g., medical devices).

**Find the optimal timing:** Licensing could be arranged as early as proof-of-concept, or later, when a product is on the market. There are several tradeoffs for innovators to consider regarding the timing of licensing. An innovation still at an early stage of development has limited data on technical feasibility or commercial attractiveness, which would most likely lead to lower financial gains from the licensing deal. On the other hand, licensing early has at least three benefits: freeing time and resources that would otherwise go into reaching more advanced product development milestones, off-loading some risk to the licensee, and tapping into the licensee's complementary capabilities. Phoenix Medical Systems signed a licensing agreement with D-Rev when Brilliance was still in product development, and co-invested with D-Rev to complete product development, clinical testing, and regulatory affairs, which improved product design and accelerated its time to market.





# SCALING MODEL 4: OPEN LICENSING



## How do I want others to use my IP?

### What goals do I want to achieve by opening up the IP? E.g.:

- Maximize the scale of impact beyond my own reach
- Building my brand
- Attract others to further innovate and improve the technology
- Allow the technology to be used with a different scope

### In what ways do I want others to use the IP? Common restrictions to state in an open license to ensure proper use:

- Type of user (e.g., legal status of the organization)
- Components of the technology
- Geography
- "Field of use", or use cases
- Pricing
- Rights over modifications or derivatives



## Who am I trying to attract?

### What types of IP adopters are aligned with my goals? E.g.:

- Other innovators working to address a similar problem
- Target users/beneficiaries of the technologies
- Organizations that serve the target users/beneficiaries
- Players along the value chain looking to integrate upstream or downstream

### Which organizations or individuals do I most want to attract?



## What do I need to provide?

### Which of my preferred IP adopters are interested in using it and/or contributing to it? What motivates them? E.g.:

- Compelling social and/or commercial value
- The technology addresses a specific need for them and/or their partners
- Their ability to implement the technology and/or contribute to its improvement

### What do I need to provide to attract and support potential adopters? E.g.:

- Technical viability (through proof of concept or pilot trials)
- Potential impact
- User demand / existence of market
- Documentation, and the resources to help others access the IP
- Support function to answer questions and help others adopt the IP
- Platform for further collaboration

### What milestones do I need to reach to open up the IP in a way that is useful to potential adopters?

### Do I need to make changes to my current legal structure (e.g. start a new entity that owns the IP) to reach these milestones?



## What timing should I aim for?

### Are there benefits to opening up the IP early vs late? Considerations include:

- Optionality to explore other scaling models that require a more restricted IP
- Feasibility for others to adopt and/or contribute to the technology
- Attractiveness of the technology for others to adopt and/or contribute to it
- Amount of time and resources I am willing to spend to reach each milestone



## What types of funding do I need and when?

### How much additional funding do I need to raise to reach the milestones required for an open IP?

### How much more funding, if any, would I need to raise after opening up the IP?

### Given the stages at which I need funding, which types of capital should I seek?

- Friends and family money
- Competitions and prize money
- Grants
- Program-related investments
- Impact capital
- Angel equity
- Equity investor
- Debt investor
- Revenue-based financing
- Convertible debt

### What terms and restrictions would each type of capital come with?

- IP openness
- Growth strategy
- Payment timeline and schedule, interest rate (for debt)
- Valuation, voting rights (for equity)

**Decide which permissions and restrictions you want to give:** Innovators deciding to open up access to their intellectual property need an open license to do so.<sup>1</sup> Broadly speaking, an open license is one that grants permission to access, reuse and redistribute work with a few or no restrictions (definition from [Opendefinition.org](http://opendefinition.org)). Depending on the nature of the IP and the goals of the innovator, specific permissions and restrictions differ. As a result, many open licenses have been created to cater to different purposes.<sup>2</sup> For example, some licenses require modifications or derivative works be put under the same license as the original work (e.g., the GNU General Public License), while others do not (e.g., the Apache license). We encourage innovators interested in open licenses to seek out legal resources and counsel to help them choose a suitable existing open license to use as is, or adapt.

**Anecdote:** *During the first five years, OpenMRS chose to adopt the Mozilla Public License Version 1 (MLP1}. Given the healthcare use case of OpenMRS, the founders added two additional clauses to MLP1 to protect from medical liability. In 2012, OpenMRS moved to Mozilla Public License Version 2, a standard and simpler license approved by the Open Source Initiative, with an addendum containing healthcare-related disclaimers. This open license allows additional modules developed outside the OpenMRS source code files to be assigned any license, which encourages innovation by a wider range of entities, including those interested in scaling up through commercialization.*

**Understand and cultivate sources of support and learning:** While open licensing requires no further involvement by the original creators, those aiming to accelerate adoption and maximize the impact of their innovations will need to invest time and effort in cultivating an open and collaborative community. An open project has the potential to attract crowds of supporters from expected and unexpected sources. For example, by participating in Google's "Summer of Code", OpenMRS tapped into a pool of talented volunteer engineers beyond the founders' expectation eager to contribute to the project. Over the years, several software firms made license donations to OpenMRS, which was also unanticipated at the start of the project. Innovators should proactively identify the full range of potential contributors and configure the community infrastructure to draw in, support and connect contributors with each other (e.g., provide peer-learning mechanisms for community members to share successes and failures, understand how local context affects the impact of the innovation, and catalyze further innovations).

**Design an appropriate impact-tracking mechanism:** With few restrictions contained in open licenses, the original creators cannot easily find out how and by whom the innovation is being used, other than count the times the files were downloaded. To collect more information on the use and impact of their technologies, innovators need to design tracking mechanisms and communication channels with potential users. These are best posted when the open content is published, and could be included in the open license agreement.

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1 Without an explicit license, works are usually subject to the copyright laws of the jurisdiction they are published in by default. These laws typically give several exclusive rights to the copyright holder and prohibit unauthorized re-distribution and re-use by third parties. Open licenses enable creators to allow more freedom in what others can do with their works.

2 For a list of the most common open licenses, go to <http://www.opendefinition.org/licenses>

# SCALING MODEL 5: GETTING ACQUIRED



## What do I need in an acquirer?

How much do I want to stay involved post-sale?

What part of my organization do I want to sell? E.g.:

- The entire organization, including assets
- IP only

What characteristics would an ideal acquirer have? E.g.:

- An attractive financial offer
- Financial health
- Size, maturity
- Brand and reputation
- Potential to collaborate in the future
- Footprint in target geographies
- Product portfolio

What values does the acquirer need to have? Signs of value alignment:

- Vision of success for my product
- A customer base that aligns with my target users
- Willingness to let me influence strategy



## Which acquirers likely meet my needs?

Which types of acquirers would likely meet my needs? E.g.:

- Multi-national corporations
- Local manufacturers/distributors
- Innovation, R&D, design entities
- Investor (e.g. private equity)

How do I create a short list of organizations I should consider selling to?

Which organizations on the list are most aligned with my criteria?



## What value do I need to show potential acquirers?

Which of my preferred acquirers are interested in my technology/organization?

What motivates them? E.g.:

- Compelling commercial value
- Strategic alignment with existing markets / customer base
- Compatibility with existing product portfolio

What do I need to demonstrate to potential acquirers? E.g.:

- Technical viability (through proof of concept or pilot trials)
- Potential impact
- Strategic relevance to the acquirer, in terms of geographies, health issues, target markets, etc.
- User demand / existence of market
- Commercial sustainability and attractiveness
- Pathway to regulatory approval
- Manufacturability

What milestones do I need to reach to demonstrate evidence in these areas?

Do I need to make changes to my current legal structure (e.g. start a new entity that owns the IP) to reach these milestones?



## What timing should I aim for?

Are there benefits to selling early vs late? Considerations include:

- Optionality to explore other scaling models
- Potential financial return
- Bargaining power in the negotiations
- The time and resources I am willing to spend to reach each milestone



## What types of funding do I need and when?

Do I need to raise additional funding to reach the milestones required to sell my product?

Given the stages at which I need funding, which types of capital should I seek?

- Friends and family money
- Competitions and prize money
- Grants
- Program-related investments
- Impact capital
- Angel equity
- Equity investor
- Debt investor
- Revenue-based financing
- Convertible debt

What terms and restrictions would each type of capital come with?

- IP openness
- Growth strategy
- Payment timeline and schedule, interest rate (for debt)
- Valuation, voting rights (for equity)

**Determine which aspects of the organization to sell:** An innovator seeking to be acquired needs to first determine what aspects of the organization to sell – intellectual properties (sold through a full technology transfer), physical assets, and/or the organization itself. The answer depends on the innovator’s preferences and the interests of potential buyers. For example, if the innovator wants to retain the organization’s core product development capabilities, he/she would choose to sell a specific IP to an individual buyer. If potential buyers value the talent and infrastructure built up to support an innovation, then they would be interested in buying the entire organization.

***Anecdote:** Sushrut sold its business "wholesale" to Smith and Nephew. Smith and Nephew was interested in entering the Indian market for surgical equipment, and wanted to buy the extensive sales and physician engagement infrastructure that Sushrut had built up over the years, in addition to its orthopedic implant products. After a brief post-sale transition period, the owners left the company, but all Sushrut employees remained to work as part of Smith and Nephew.*

**Understand the investment criteria of acquirers and the implied milestones:** As with other scaling models, innovators need to perform due diligence on prospective acquirers to understand why they are interested and what they are seeking. For corporations seeking commercial opportunities to consider a global health acquisition, the product or technology must support the corporate strategy and contribute to the company’s financial performance and growth. This usually implies that the product or technology can fill a gap in the company’s portfolio and give it access to new markets. Potential gains are weighed against risks and investments. For example, a potential acquirer may not have the distribution capabilities needed to scale-up the product or technology in target markets, and will need to make sizable investments to create such capabilities. To demonstrate strategic alignment, innovators need to show many types of evidence, including technical viability (i.e., that the product or technology works), IP ownership (i.e., the innovator has defensible ownership over the applicable IP for the product or technology), a value proposition for the relevant markets (i.e., the product or technology would bring a compelling and recognizable health impact and economic value to target users), a regulatory pathway (i.e., the product or technology will gain regulatory approval in target countries by following a set of well-understood pathways), and manufacturability (i.e., the product or technology can be made at commercial scale). Each of these dimensions could require the innovator to invest considerable time and resources, depending on the robustness of the evidence required. Innovators should ask prospective buyers to divulge their investment criteria early on so they can determine whether to pursue this pathway to scale, and if so, understand all the challenges it would entail.

**Find the optimal timing:** Similar to licensing, a company can be acquired early, when the products are still in proof-of-concept, or late, when the products are being sold on the market. The tradeoffs that innovators should consider when timing the sale of their innovations are similar to those for licensing (see page 45).



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