Case 2-5: Torrey Nano, Inc.*

Jack Heiner, the CEO of Torrey Nano, a seven-year-old biotechnology firm, faced an important decision in the spring of 2017. Torrey Nano, based in San Diego, California was a company of 35 employees, most of whom were research scientists. Torrey Nano's pharmaceutical product, codename Nano-4, was almost ready for human testing. The company aspired to be a full-fledged pharmaceutical company. However, like most biotech startups, it had focused on R&D since its founding. Consequently, it had done no manufacturing or marketing. With the impending human testing of Nano-4, however, it faced the decision of whether to build a small-scale pilot plant to manufacture Nano-4 for human trials. Nano-4 was the fourth product that Torrey Nano had developed but the first to advance to human trials. The drug had multiple potential therapeutic applications, but Torrey Nano had focused on diabetes treatment as its first application. The company had three other products in earlier stages of development.

Human testing involved three phases. Phase I, which lasted from 6-12 months, assessed basic human safety (e.g., adverse side effects, etc.). If a product was approved in Phase I, it moved to Phase II where the drug was tested with a small group of patients. Phase II examined the efficacy of a drug in treating a disease and also evaluated whether serious side effects occurred. Phase II usually lasted from one to two years. Products that succeeded in Phases I and II could go on to Phase III. Phase III, which could take two to five years to complete, tested the drug using a large sample of patients. Regulations required that whatever manufacturing processes were used in Phase III must be the same as those used after the drug was approved and marketed commercially.

The manufacturing of drugs based on nanotechnology was considered highly complex and uncertain. Drugs based on nanotechnology were particularly new in 2017 but were generally thought to hold great promise for a wide variety of diseases. Several reports suggested that manufacturing nano-materials was both difficult to replicate and scale. Thus, it was challenging to develop effective processes for manufacturing new nano-drugs. Some nanotechnology drugs, while feasible to make in the small quantities needed for pilot studies, were especially problematic to manufacture on a large scale. Very small differences in processes could lead to failure. Moreover, industry experts reported that firms often had difficulty transferring a manufacturing process from one facility to another. Few young companies had experience manufacturing products of the type of Nano-4. There were, however, a handful of contract manufacturers who had some experience in manufacturing involving nanotechnology. Even for these firms, though, it often required considerable trial and error before mastering the process for a particular drug.

Torrey Nano managers identified five possible scenarios for how they might handle the manufacturing of Nano-4. The five scenarios are listed here with cash flow estimates included in Table 1.

Scenario 1: Torrey Nano builds a pilot plant for Phases I/II and a full-scale plant for Phase III.

Scenario 2: Torrey Nano builds a pilot plant for Phases I/II and licenses out the manufacturing rights for Phase III.

Scenario 3: Contract out manufacturing for Phases I/II, build a full-scale plant in-house for Phase III.

Scenario 4: Contract out manufacturing for Phases I/II and license out manufacturing rights for Phase III.

Scenario 5: Manufacturing in all phases would be done by licensee.

In all five scenarios, Nano-4 would ultimately be distributed and marketed by an established pharmaceutical firm that would serve as Torrey Nano's and/or the eventual manufacturer's, marketing partner. If Nano-4 successfully navigated clinical testing to reach the commercial stage, analysts projected sales ranging from $75 million in 2025 to over $288 million in 2035, the last year of patent protection (see Table 2). As Heiner contemplated his options, it was clear that the scenarios involving in-house manufacturing were costlier, but potentially more lucrative. Both of the first two scenarios required capital investments in 2018 and 2019 to build a pilot plant while scenarios 1 and 3 required large capital outlays to build a full-scale plant in 2020 and 2021 (see Table 3). Cash flow projections suggested that building a full-scale plant would allow Torrey Nano to capture a higher percentage of the revenue stream for Nano-4—$15 million licensing fee from its marketing partner in 2025 upon successful completion of clinical trials and 40 percent of royalties. Licensing the manufacturing rights after Phase II, as required by Scenarios 2 and 4, would yield a lower payout—$10 million licensing fee from the marketing partner and 10 percent royalties.

* This case is intended for class discussion only. Torrey Nano is a fictitious company and, while nanotechnology is believed to offer great promise for the future in pharmaceuticals, technical details in the case may not reflect reality.

Table 1 Forecasted Cash Flows for Torrey Nano Investment Scenarios

Phase I/II	Torrey Nano	Torrey Nano	Contractor	Contractor	Licensee
Phase III	Torrey Nano	Licensee	Torrey Nano	Licensee	Licensee
Year	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5
2018	−5,000	−5,000	0	0	5,000
2019	−3,000	−3,000	−4,000	−4,000	0
2020	−33,000	−3,000	−34,500	−4,500	0
2021	0	0	0	0	0
2022	0	0	0	0	0
2023	0	0	0	0	0
2024	0	0	0	0	0
2025	45,000	17,500	45,000	17,500	3,750
2026	56,000	14,000	56,000	14,000	7,000
2027	70,000	17,500	70,000	17,500	8,750
2028	78,000	19,500	78,000	19,500	9,750
2029	86,000	21,500	86,000	21,500	10,750
2030	90,300	22,575	90,300	22,575	11,288
2031	94,815	23,704	94,815	23,704	11,852
2032	99,556	24,889	99,556	24,889	12,444
2033	104,534	26,133	104,534	26,133	13,067
2034	109,760	27,440	109,760	27,440	13,720
2035	115,248	28,812	115,248	28,812	14,406

Table 2 Projected Sales from Nano-4 (in 000's)

2025	$75,000
2026	$140,000
2027	$175,000
2028	$195,000
2029	$215,000
2030	$225,750
2031	$237,038
2032	$248,889
2033	$261,334
2034	$274,401
2035	$288,121

A pilot plant with sufficient capacity to produce output for Phases I and II involved a $5 million investment in 2018. This investment would cover all expenses including facilities and plant equipment. The company would still incur $1 million in production costs in 2019 and 2020 as well as $2 million in expenses for the clinical trials in those years. A larger-scale plant for Phase III and commercialization would require a $30 million investment in 2020. Torrey Nano had sufficient funds for the Phase I/II investment. The Phase III investment would require another round of venture capital funding. Heiner and Torrey Nano's board, however, were convinced that such funding was highly likely if Nano-4 successfully completed Phase I/II testing. Venture capitalists expected returns of 30%, which a successful pharmaceutical product would insure for a biotech firm such as Torrey Nano.

Table 3 Details for Cash Flows for Each Decision Scenario (in 000's)

	2018	2019	2020	2025	2026-35
Scenario 1					
- Pilot Facility Construction Costs	−5,000				
- Production Costs		−$1,000	−$1,000		
- Clinical Trials		−2,000	−2,000		
- Phase III/Commercial Plant Construction Costs			−30,000		
- Licensing Fee				15,000	40%
- Royalties				40%	
Scenario 2					
- Pilot Facility Construction Costs	−5,000				
- Production Costs		−$1,000	−$1,000		
- Clinical Trials		−2,000	−2,000		
- Licensing Fee				10,000	10%
- Royalties				10%	10%
Scenario 3					
- Contract Production		−2,000	−2,500		
- Phase I/II Clinical Trials		−2,000	−2,000		
- Phase III/Commercial Plant Construction Costs			−30,000		
- Licensing Fee				15,000	
- Royalties				40%	40%
Scenario 4					
- Contract Production		−2,000	−2,500		
- Phase I/II Clinical Trials		−2,000	−2,000		
- Licensing Fee				10,000	10%
- Royalties				10%	10%
Scenario 5					
- Licensing Fee	5,000				
- Royalties					5%

Heiner believed that building a pilot plant (Scenarios 1 and 2) would allow Torrey Nano to develop the foundation for future large-scale manufacturing capabilities. While the company's 35 employees were mostly technically sophisticated research scientists, none had any significant experience in manufacturing. The company did not have any employees with the variety of operations management skills needed for manufacturing. A pilot plant would allow Torrey Nano to hire people and develop organizational capabilities in manufacturing. Building a pilot plant was not without challenges and risks, however. The process challenges involved in producing Nano-4 at even pilot scale were somewhat uncertain and might pose challenging for a firm with early capabilities in manufacturing. Some within the company believed that manufacturing was outside of the company's capabilities and that Torrey Nano should stick to what it did best, which was R&D.

Contract manufacturing (Scenarios 3 and 4) was a second option for Phase I/II. Contracting required little to no capital investment on Torrey Nano's part. Several contract manufacturers had idle capacity, and some had experience with the challenges of scaling nanotechnology. Contracting was expensive. Torrey Nano forecasted paying production costs of $2 million in 2018 and $2.5 million in 2019. The

company would also pay $2 million each year for clinical trial expenses. Because of the uncertainties involved in manufacturing a new drug, formulating a contract that was satisfactory to the two firms involved could be a lengthy process. Even with the most well-intentioned efforts, a contract was likely to fail to foresee important contingencies. Such failures in foresight would trigger considerable negotiation between the firms. Contracting also necessitated the sharing of a considerable amount of sensitive proprietary information. Such information could help potential competitors and contractors gain a more advantageous position against Torrey Nano.

Scenario 3 was a compromise between outsourcing and in-house manufacturing. In this scenario, Torrey Nano would contract out the manufacturing for Phases 1 and 2, but vertically integrate for Phase 3 and commercial manufacturing. The costs for Phases I/II were the same as in Scenario 2, but the costs and payout in Phase III and commercialization were identical to those in Scenario I. The appeal of this option is that it would allow Torrey Nano to avoid the significant capital investments involved in developing a pilot plant yet reap the higher royalties (forecasted at 40 percent) that doing manufacturing in-house would yield. Construction on a commercial-scale plant would need to begin as soon as possible after the completion of Phase II trials. The challenge involved in Scenario 3 is that it required Torrey Nano to make the leap to manufacturing on a larger-scale without first developing its capabilities at a smaller scale.

Scenario 4 involved contracting out manufacturing for Phases I/II and then licensing out the manufacturing rights for Phase III and commercialization. In this scenario, Torrey Nano would not need to develop manufacturing capabilities and would not have to incur the $5 million costs of a pilot plant or the $30 million investment associated with Phase III.

Scenario 5 involved entering in a license deal immediately. In this scenario, the licensing partner would bear all the costs and risks involved in manufacturing and regulatory approvals for Phases I, II, and III as well as commercialization. Torrey Nano would receive a $5 million payment and 5 percent royalties from future sales of Nano-4. However, Torrey Nano would forego the opportunity to capture the much higher royalties associated with the other scenarios.

As Heiner reflected on Torrey Nano's scenarios, he realized that they involved important tradeoffs. Some of the scenarios offered a potential stepping stone for the company to realize its aspiration of becoming a stand-alone pharmaceutical firm. Other options increased the company's chance of survival, and would guarantee the company the ability to develop other products. Heiner wondered if other products in the pipeline had as much or more potential than Nano-4. It was difficult to say. What did Heiner's employees want? All were impressive scientists with abundant opportunities at other firms. They gravitated to Torrey Nano because the scientific problems it addressed were both exciting and important. In many cases, though, the scientists were looking to combine interesting science with the opportunity to make their fortunes in the right startup. As Heiner pondered these questions, he realized that the time for analysis was over. He had to decide.