A Strategic Review of Outsourced Manufacturing for Medical Devices

How Broad Industry Trends Will Benefit Buyers and Sellers Alike

By Benjamin Dunn and John Finn

© 2007 Covington Associates LLC. All rights reserved.
TABLE OF CONTENTS

Executive Summary 1
Introduction 3
Device Industry Trends 4
  Strategic Rationale For Outsourcing 6
  Contract Manufacturing Segment 8
  Economics Of Outsourced Manufacturing 10
A Buyer’s Perspective 13
  Enhancing Value 15
  Buyer Risks 17
The Operator’s Dilemma 19
  Niche Manufacturing 19
  Full-Service Manufacturing 20
Conclusion 22
EXECUTIVE SUMMARY

The Medical Device industry has undergone substantial growth in the last decade. Estimates put the size of the global device market in excess of $170 billion as of 2005, with the U.S. market accounting for 44% with roughly $74 billion, up from $48 billion in 1995. In the face of mounting operating expenses, industry profits are being driven by a combination of product innovation and creative cost cutting measures, including the increasingly popular strategy of outsourced manufacturing. Structural factors within the device industry are creating a pivotal role for the contract manufacturing segment, generating much attention from a diverse but related group of stakeholders including incumbent market leaders, branded OEMs (Original Equipment Manufacturers) and private equity groups.

Industry Trends

Several coincidental factors make the contract manufacturing segment attractive to investors. Economic need on the part of OEMs, a greater than average growth rate relative to the larger industry, and the potential for significant consolidation will drive buyouts for the foreseeable future. Contract manufacturers have benefited from the growth of device end markets, yet growth of the segment continues to outpace that of the broader device market as a whole, demonstrating an increasing trend towards outsourcing. As of 2005, an estimated 20% of all OEM manufacturing was outsourced to third-party vendors, resulting in annual market growth of 26% to $4.4 billion in 2005 from $2.2 billion in 2002. Covington Associates believes that as much as 40% of all manufacturing could be outsourced by 2010, leading to 15% annual growth from current levels.

Intense competition among device OEMs has placed even greater emphasis on the core competencies of clinical education, R&D, sales, and marketing. One of the primary drivers of the trend to outsource manufacturing operations is the need to reduce direct expenses and streamline supply chains while offsetting mounting operating expenses. The industry has improved gross margins over time due to productivity gains and shifts in product mix, yet these gains may face eventual erosion as competition drives expenses higher in an environment of pricing and reimbursement pressures.

Market Structure

The medical device contract manufacturing segment is highly fragmented with thousands of independent operators competing for a piece of the OEM outsourcing opportunity. The combination of increasingly sophisticated products and greater dependence of OEMs on their manufacturing partners has resulted in a growing tendency to partner with larger, full-service manufacturers which continue to expand their breadth of service offering and depth of product expertise. The result is a
handful of dominant players that control roughly 50% of the market, with the balance consisting of participants that control less than 1% market share each.

Mergers and Acquisitions

Acquirers of contract manufacturing businesses have recognized the confluence of increased market demand for outsourced services and a favorable industry structure for concentration. Strategically, operators have identified two routes to success in this segment, namely diversification of operations in the form of full-service providers or specialization as expert niche manufacturers. In both instances, driving scale to achieve operational leverage is the primary goal of any acquisition strategy.

M&A activity in this segment has been gaining momentum in recent years, but there remains significant fragmentation and therefore opportunity for further consolidation. Financial and strategic buyers, often platform companies controlled by financial sponsors, have been opportunistic, and in a race to achieve critical mass have been bidding up the values of those targets that exhibit the most favorable criteria. Median valuation multiples of 12-month trailing EBITDA (Earnings Before Interest, Taxes, Depreciation, and Amortization) are at the upper end of the middle-market deal spectrum, leading many to question whether or not the current buyout market favors buyers or sellers. Historically high valuation multiples suggest that sellers have the advantage, but a closer examination of the underlying industry dynamics suggest that both sides stand to gain significant rewards.
INTRODUCTION

The concept of outsourced manufacturing is hardly new to the U.S. economy. For decades, the automotive, defense, apparel and electronics industries have relied heavily on outsourcing to contain production costs and streamline supply chains. In the medical device industry, contract manufacturing adds another dimension to an increasingly competitive market, allowing device OEMs to focus on their core competencies of R&D, technology, sales, and marketing. The trend is proving to be a vital strategic tool being that a competitive advantage is based as much on timing of product launch as it is on product cost.

In the traditional sense, contract manufacturing is the supply of dedicated production capacity and expertise by third-party service providers as a means to supplement (or entirely replace) in-house manufacturing operations. While the model has developed over time to include ancillary services such as product design, prototyping, and packaging, it fundamentally thrives on the combination of high production volumes and standardized processes in order to achieve economic viability. These two elements are the key to a contract service provider’s ability to produce a single unit at a lower cost than is achievable by an OEM. The impact on an OEM’s gross margin is direct and positive, but the story goes further.

Factoring in quicker production ramp-up, lower capital expenditures, access to highly skilled labor markets and raw materials, expert design teams and global distribution networks, there is little doubt that contract manufacturing provides a compelling value proposition for OEMs. That is not to say the model is without inherent risk. As with any outsourcing partnership, a lot needs to go right for the initiative to succeed. Regulation, performance standards and supply chain integration are just some of the issues that make contract manufacturing a challenging environment to conquer. That said, outsourcing is a generally accepted alternative and is being used in a greater range of areas to provide a greater range of solutions for major device OEMs.
DEVICE INDUSTRY TRENDS

The rising popularity of outsourced manufacturing is best examined in the context of broad industry trends that are shaping the future business models of medical device manufacturers. Double digit growth rates in certain market segments, an increasing rate of product development, industry consolidation among OEMs as well as pricing and regulatory pressures are all contributing factors.

Market Growth is Outpacing Capacity Expansion
Growth of the broader device industry is being fueled by population demographics, product innovation, and significant market potential outside the United States. High estimated growth in device end markets, such as cardiovascular, endoscopy, and orthopedics, is challenging many OEM’s ability to plan and meet long-term internal manufacturing capacity requirements. Furthermore, any expansion of internal capacity over the long run will require significant capital investment which could otherwise be invested in new product development.

Operating Margins are Under Pressure
Historically, OEMs have achieved revenue growth through a combination of corporate acquisitions and product price increases. Coincidentally, governments, third-party payers and healthcare providers consistently push for price concessions in an effort to reduce the effect of rising healthcare costs across the industrialized world. Consistent revenue growth is supported by technical innovation, whereby older technologies are relegated to use in commodity items, and new technologies drive growth through premium pricing strategies.

The industry has generally improved gross margins over time due to productivity gains and shifts in product mix, yet gains in gross margin face eventual erosion as competition drives operating expenses higher in an environment of increasing pricing and reimbursement pressures. Competition in the device industry is fundamentally based on the expiration and infringement of patents, the primary driver of the research and development of new products. The dual effect of pricing pressure and rising costs suggests that firms within the industry must increasingly exploit sources of cost leadership such as economies of scale, proprietary technology and lower product acquisition costs in order to remain competitive.
Shortening Product Lifecycles

Technological parity among competing products implies that time to market is critical for the majority of device product lines. OEMs are stepping up new product development, seeking ways to get their products to market more quickly so as to gain share ahead of entry by equally effective devices. For example, in 2006 roughly two thirds of the revenue of Medtronic, a leading medical device company, came from products introduced within the previous twenty four months. At that rate, Medtronic stands to replace their entire source of revenue every three years, a phenomenal rate by any standard. The shortening product lifecycles requires significant R&D capabilities, not to mention the extent to which production flexibility, or the lack thereof, could materially affect the success of devices aimed at narrowing windows of opportunity.

Figure 1: OEM Cost Structure is Changing

Source: Company filings
Note: Device OEMs include Baxter International, Biomet, Boston Scientific, CR Bard, Medtronic, Stryker, Varian Medical Systems and Zimmer Holdings
Consolidation Creates Supply Chain Challenges for OEMs

Industry consolidation continues among OEMs for a number of reasons, including:

- Using scale to drive operating leverage
- Gaining access to new technologies
- The convergence of biopharmaceuticals and devices
- Cost of developing distribution channels
- The generally large universe of small and medium-sized companies unable to complete the development of promising products

An issue for any acquirer - typically larger and in a stronger financial position - is the integration of disparate manufacturing and supply chain networks. This issue has the potential to create an organizational focal point that draws attention away from an acquirer’s core competencies, being the development and marketing of innovative products.

STRATEGIC RATIONALE FOR OUTSOURCING

Beyond simply lowering product acquisition costs, contract manufacturing has a number of strategic benefits that serve as incentives for OEMs to outsource their production. These include:

1. **Shorter time to market.** Engaging full-service contract manufacturers in the design and development phase of a product’s lifecycle can do much to condense launch timelines. Furthermore, manufacturing experts working in conjunction with product designers are better able to achieve productivity gains by implementing design-for-manufacture techniques and driving out production inefficiencies over the long-term.

2. **Ability to focus on core competencies.** Medical device OEMs earn greater returns on capital by investing in product development and marketing than in manufacturing. Establishing manufacturing capacity is both capital intensive and slow going, resulting in a lower ROI (Return on Investment) over a longer period of time.

3. **Rationalized supply chain.** An emerging trend among larger contract manufacturers is the greater assumption of critical supply chain functions (see Figure, pg. 11). Moving toward a “one-stop” model makes both practical and financial sense to many device OEMs that would prefer to minimize the time and effort required to manage manufacturing and supply chain operations.

4. **Access to specialized capabilities.** Contract manufacturers are able to become experts in certain market niches, allowing OEMs access to specialized production capabilities without spending valuable R&D dollars on projects that distract from their core competencies.

5. **Production Flexibility.** Contract manufacturers are able to utilize their capacity more efficiently based on a consistent flow of orders. They can accommodate large orders when called upon.
While the argument for outsourced manufacturing is compelling, there are instances in which an OEM may choose to in-source projects for which it would otherwise rely on a contract manufacturer. They include:

1. *Excess capacity.* Given the fixed-cost nature of manufacturing, an OEM may choose to leverage under-utilized resources before outsourcing the work.

2. *Control of manufacturing.* OEMs may in-source to more efficiently implement mid-stream process changes. This would occur on a case-by-case basis given that many larger outsourcing partners are becoming tightly integrated into the overall supply chain, including co-development of products.

3. *Liability concerns.* OEMs are ultimately liable for products they market, and there may be instances, such as intense scrutiny of a product line, that could warrant ownership of the manufacturing process.
**CONTRACT MANUFACTURING SEGMENT**

**Segment Structure**

In terms of participants, the medical device contract manufacturing segment is highly fragmented with literally thousands of independent operators competing for a piece of the OEM outsourcing opportunity. There are currently in excess of 3,000 firms engaged in the business of machining, stamping, assembling, sterilizing, and packaging medical devices. These firms range in size and complexity from relatively small owner-operated machine shops, to larger niche manufacturers of specialty components to highly sophisticated, professionally managed organizations offering a broad range of services under one roof.

Approximately 50% of the market is controlled by no more than 12 firms, with leader Accellent Inc. controlling 12% of the market, estimated to be roughly $4.4 billion as of 2005. Accellent is considered the model of success in the medical device contract manufacturing segment, growing from a small contract manufacturer to a fully integrated “one stop shop” with the help of a financial partner. Accellent’s nearest competitor, Symmetry Medical, services customers almost exclusively in the orthopedics market. The remainder of market is highly fragmented, comprised of firms that enjoy less than 1% market share each, which effectively establishes two tiers of participant: large full-service organizations and small niche service providers.

*Figure 2: Contract Manufacturing Market Share in 2005*

Source: Millennium Research, Frost & Sullivan, Accellent
Market Size and Growth

The exact market for outsourced medical device manufacturing remains unclear, yet consensus estimates put it at approximately $4.4 billion as of 2005, up from $2.2 billion in 2002. Primary drivers of the segment’s growth include not only the growth of the overall device market but the degree to which device OEMs elect to outsource their manufacturing operations. As outsourcing gains acceptance among OEMs, its growth rate will exceed that of the medical device industry. Research suggests that gross profit for all medical devices sold in the U.S. was a little over $52 billion in 2005, or roughly 70% of sales. This translates into approximately $22.2 billion COGS (Cost of Goods Sold) for device OEMs. Assuming a $4.4 billion market size for contract manufacturing, we can deduce that the production of approximately 20% of all devices sold in the U.S. in 2005 was outsourced to third parties.

Looking ahead to 2010 it is estimated that the market for outsourced manufacturing will grow at 15% annually to $8.9 billion from $4.4 billion in 2005. Assuming modest gross margin gains (due in some part to the continued trend to outsource), we can reasonably expect OEM gross margins to approach 74% on average (Note: Improvement of OEM gross margins, *ceteris paribus*, reduces the size of the outsourcing opportunity). With estimated device revenues of around $86 billion in the U.S. by 2010, a 40% COGS penetration rate translates into a potential market size of $8.9 billion, more than double the current market size.

<table>
<thead>
<tr>
<th></th>
<th>2002</th>
<th>2005</th>
<th>2010E</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Device Revenues</td>
<td>$67.1</td>
<td>$74.0</td>
<td>$86.0</td>
</tr>
<tr>
<td>OEM Gross Margin</td>
<td>68.6%</td>
<td>70.0%</td>
<td>74.0%</td>
</tr>
<tr>
<td>OEM COGS</td>
<td>21.1</td>
<td>22.2</td>
<td>22.4</td>
</tr>
<tr>
<td>COGS Penetration</td>
<td>10.4%</td>
<td>19.7%</td>
<td>40.0%</td>
</tr>
<tr>
<td>Contract Manufacturing Market Size</td>
<td>$2.2</td>
<td>$4.4</td>
<td>$8.9</td>
</tr>
</tbody>
</table>

Source: Medical Device market size and gross profit from IBISWorld estimates. Contract manufacturing market size based on consensus among Frost and Sullivan, Millenium Research, MedTech Insight and Accellent estimates.
ECONOMICS OF OUTSOURCED MANUFACTURING

As expected, the margin profile of device OEMs differs greatly from that of their outsourcing partners. Intellectual property, pricing strategy and customer concentration play major roles in determining how budgets are allocated and margins achieved.

There are two main profiles of medical device contract manufacturers. The first is not unlike any other outsourced manufacturing operation, where high volume and low margins are characteristic traits. For OEMs, COGS constitute a relatively small portion of revenue due to the ability to maintain premium pricing. Contract manufacturers that lack intellectual property compete, to a large extent, on the basis of pricing as the primary differentiator. Without substantial value-added services, firms are unable to distinguish themselves in a sea of competition, and are generally unable to break out of the high volume/low margin tradition. A second profile of medical device contract manufacturers is niche players who produce low volume, highly specialized products. These companies may offer specialized expertise or services, hold proprietary intellectual property, or have solid relationships with customers that differentiate them as niche providers.

Figure 4: Comparison of Expenses: OEM versus Contract Manufacturing (CY2006)

Source: Company filings
Note: Figures are medians. Device OEMs include Medtronic, Stryker, Zimmer, St. Jude Medical, Biomet, Edwards Lifesciences and Smith & Nephew. Contract Manufacturers include Accellent, Symmetry Medical, Synovis Life Technologies and Plexus.
Advent of the Full-Service Contract Manufacturer

Having identified the opportunity to manipulate their own cost structures, leading contract manufacturers are attempting to broaden their service offerings to include R&D, engineering and supply chain management, value-added services that not only exhibit higher margin potential but enable an increase in the number of entry points into the OEM cost structure. No longer will full-service manufacturers be competing solely for the opportunity to lower OEM product acquisition costs. In an increasing way, top-tier manufacturers are competing for the opportunity to co-develop products, patent manufacturing processes, and establish distribution networks to handle finished goods.

Figure 5: Full-Service Contract Manufacturers are Assuming a Greater Role in the Supply Chain

With an increasingly strategic view of contract manufacturing, OEMs are more likely than ever to establish long-term contracts with their outsourcing partners. The benefits of working with a limited group of suppliers extend beyond mere supply chain efficiencies. Rigid quality standards in a highly regulated environment call for a significant degree of trust and oversight in establishing supply agreements. Consequently, OEMs go to great lengths in choosing contract manufacturing partners, often including specific vendors in the 510K process.
The switching costs of moving production from one manufacturing facility to that of a competitor are generally quite high. As a consequence, the strong relationships that develop between original and contract manufacturers are especially attractive to potential buyers who seek barriers to competition, access to an otherwise inaccessible customer base, or both.
A BUYER’S PERSPECTIVE

Acquirers of contract manufacturing businesses have generally recognized the confluence of increased market demand for outsourced services and a favorable industry structure in terms of concentration. Strategically, operators have identified two routes to success in this segment, namely diversification of operations in the form of full-service providers or specialization in the form of niche manufacturing. In both instances, driving scale to achieve operational leverage is the primary goal of any acquisition strategy.

Market Fragmentation

As with any fragmented market, the opportunities to create value through consolidation hinges on the degree to which scale and synergies make the whole worth more than the sum of its parts. With over 3,000 participants, most of whom are small proprietor-run niche manufacturers with limited access to capital, the opportunities for consolidation are enormous.

If trends in related industries are anything to go by, industry consolidation among manufacturing suppliers is inevitable. Already, the scale of engineering and manufacturing operations is playing a larger role in influencing the decisions of OEMs to outsource manufacturing to a reduced set of full-service vendors.

Precedent of M&A Success

KKR’s acquisition of Accellent Inc. for $1.27 billion in November 2005 is a textbook example of a “roll-up” and exit by fellow buyout firm KRG Capital Partners. Beginning in 1999 with the acquisition of Denver-based Star Guide Corporation (approximately $10mm revenue and $4mm EBITDA), KRG executed an additional nine acquisitions of specialist medical device contract manufacturers in an effort to build the leading full-service outfit. The addition of Medical Device Manufacturing, Inc., UTI Corporation and MedSource Technologies Inc. created what is now Accellent Inc. which provides services to some of the largest device manufacturers including Boston Scientific, Johnson & Johnson, Medtronic, and Stryker.

With trailing twelve month revenues of approximately $447 million and an EBITDA of roughly $86.9 million, Accellent’s valuation at the time of the KKR buyout represented a 14.6x multiple of trailing EBITDA. While the sheer size of the Accellent deal made industry headlines, it by no means set a precedent in terms of valuation. As Figure 6 (pg. 14) illustrates, a robust M&A market has existed for some time in the contract manufacturing arena, where deals have often exceeded the average buyout multiples set in 2006 (The average buyout multiple of EBITDA up to October 2006 was 7.3x for deals in the $0-$250mm range, 8.0x in the $251mm-$499mm range, and 8.5x for deals valued above $500mm).
A median enterprise value of 12.93x EBITDA among the deals profiled (Figure 6) indicates the extent to which acquirers are willing to pay a premium.

### Figure 6: Representative M&A Transactions

<table>
<thead>
<tr>
<th>Date</th>
<th>Acquirer</th>
<th>Target</th>
<th>Enterprise Value / Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apr-07</td>
<td>Symmetry Medical Inc.</td>
<td>TNCO*</td>
<td>0.93x NA</td>
</tr>
<tr>
<td>Jan-07</td>
<td>Riverside Partners LLC</td>
<td>J-PAC*</td>
<td>NA NA</td>
</tr>
<tr>
<td>May-06</td>
<td>Symmetry Medical Inc.</td>
<td>Riley Medical, Inc.</td>
<td>4.59x NA</td>
</tr>
<tr>
<td>Nov-05</td>
<td>Kohlberg, Kravis, Roberts &amp; Co.</td>
<td>Accellent, Inc.</td>
<td>2.84x 14.61x</td>
</tr>
<tr>
<td>Oct-05</td>
<td>Accellent, Inc.</td>
<td>Machining Technology Group</td>
<td>4.10x 10.01x</td>
</tr>
<tr>
<td>Sep-05</td>
<td>Accellent, Inc.</td>
<td>Campbell Engineering, Inc.</td>
<td>1.76x NA</td>
</tr>
<tr>
<td>Apr-05</td>
<td>West Pharmaceutical Services Inc.</td>
<td>The Tech Group, Inc.</td>
<td>1.43x 22.70x</td>
</tr>
<tr>
<td>Sep-04</td>
<td>Schooner Capital</td>
<td>Millstone Medical Outsourcing, Inc.*</td>
<td>NA NA</td>
</tr>
<tr>
<td>Apr-04</td>
<td>Accellent, Inc.</td>
<td>MedSource Technologies, Inc.</td>
<td>1.31x 11.25x</td>
</tr>
<tr>
<td>Nov-03</td>
<td>SCA North America, Inc.</td>
<td>Alloyd Co.</td>
<td>1.26x 7.41x</td>
</tr>
<tr>
<td>Oct-03</td>
<td>Celestica, Inc.</td>
<td>Manufacturers’ Services Limited</td>
<td>0.45x 19.95x</td>
</tr>
<tr>
<td>Mar-03</td>
<td>American Capital Strategies, Ltd.</td>
<td>Colorado MEDtech, Inc.</td>
<td>0.94x 16.12x</td>
</tr>
<tr>
<td>May-02</td>
<td>Cardinal Health, Inc.</td>
<td>Boron, LePore &amp; Associates, Inc.</td>
<td>0.81x 9.46x</td>
</tr>
<tr>
<td>May-02</td>
<td>Avail Medical Products, Inc.</td>
<td>Horizon Medical, Inc.*</td>
<td>NA NA</td>
</tr>
</tbody>
</table>

| Median | 1.37x 12.93x                           |                                      |                           |

* Covington Associates represented the target company in these transactions
ENHANCING VALUE

Despite the risks associated with contract manufacturing, the industry presents a considerable amount of opportunities for buyers. Acquirers investing in businesses in this industry will benefit from a number of factors driving growth in the overall medical device market, and have the chance to capitalize on opportunities that current manufacturers have not.

Successful contract manufacturers have benefited from a number of characteristics listed below:

1. **Broad Range of Service Offerings.** A broad range of service offerings is attractive to large diversified medical device OEMs, who require a broad range of manufacturing services to produce their products. OEMs prefer to outsource manufacturing to a single firm because outsourcing to a number of firms can be complicated and unnecessarily costly. A firm that provides the complete range of services that an OEM requires will be much more competitive than one that does not.

2. **Sufficient Capacity.** Sufficient capacity provides manufacturers with the flexibility to satisfy the immediate needs of OEMs. In a market where time to market is critical, manufacturers need to be able to quickly adapt their operations to fulfill the demands of OEMs. Capacity can be expensive, but can also be the difference between being competitive and not being competitive.

3. **Diversified Customer Base and End-Market Exposure.** A diversified customer base and end-market exposure can help insulate a manufacturer’s business from a downturn in a given customers product or a specific market. In addition to help protecting a manufacturer’s business, a manufacturer can benefit from the ability to cross sell its services among a large diversified customer base.

4. **Management Expertise.** Having a well organized business with a solid management team and sales force is crucial to growth in the contract manufacturing industry. Often, within highly fragmented industries, businesses can exist with only partially developed management teams, which can limit their growth. Focusing on and investing in a fully developed management team and sales force help to maximize growth in contract manufacturing.

5. **Access to Capital.** The contract manufacturing industry is growing and constantly requires capital investments as OEMs require additional services. Businesses that cannot afford to invest in this space sacrifice growth potential. Many smaller contract manufacturers recognize areas to invest in for growth of their business, but simply cannot afford it. Larger competitors will not pass on those opportunities, realizing that growth in this industry is essential for remaining competitive.
The existence of smaller underdeveloped manufacturers, which lack some or all of the aforementioned characteristics of a successful manufacturer, present sophisticated buyers with the opportunity to purchase and enhance these businesses. Acquirers are attracted to acquisition targets that offer an established profitable business with room for potential improvement. The fragmented contract manufacturing industry is saturated with ideal acquisition candidates for buyers.

**Acquirers should execute a consolidation strategy to enhance returns.**

There are several motivating factors behind any buyer’s decision to make an acquisition, but the objective to create value and generate returns is universal among all buyers. Buyers can maximize value in this space by combining complementary services provided by multiple manufacturers and providing these businesses the resources to grow. There are several acquisition candidates in this space presenting buyers with numerous growth opportunities.
BUYER RISKS

Acquisitions in any industry are seldom executed free of material risk. Contract manufacturing is no exception, being subject to risks inherent to the device industry in general and manufacturing operations in particular.

1. **Dependency on OEMs.** Market growth in the contract manufacturing segment is principally reliant on two factors: 1) the growth of the broader device market, and 2) the continued propensity of OEMs to outsource. Since contract manufacturers do not market their products directly to the consumer, they have little control over the demand for the products which they produce. More within their scope of control is the degree to which they are able to penetrate the OEM manufacturing base, although there are no guarantees that the trend to outsource will continue indefinitely.

2. **Capital Intensity.** Manufacturing businesses in general require significant capital investment in order to build out sufficient production capacity and achieve economies of scale. The fragmented market consists of numerous businesses requiring additional capital, and while this characteristic can be attractive to buyers with considerable financial resources, it can expose buyers of limited means to undue risk.

3. **Customer Concentration.** Be it a product of necessity or opportunity, contract manufacturing exhibits a tendency of firms to focus on a limited number of customers which are usually responsible for a considerable portion of total revenues. This dependency creates a risk as to the certainty of future earnings and poses a serious threat to the viability of any business in which capacity utilization is a make-or-break factor. The sense of fragility is magnified in cases where the operation is dependent on customers who are exposed to particularly volatile device markets.

4. **Reimbursement Policies.** Industry-wide cost containment measures could negatively effect device sales and, in effect, exert pressure on contract manufacturers to reduce pricing. Healthcare spending has dramatically increased recently and healthcare payers have become reluctant to reimburse particular devices. The pressure exerted by healthcare payers on OEMs can be sufficiently great so as to eliminate certain lines of business, including the outsourced production thereof.

5. **Shift of Product Mix to Low Margin Products.** Traditionally, low technology products have made the most likely candidates for outsourced production. Manufacturing processes are relatively simple, margins relatively low, and volume relatively high. OEMs risk less in outsourcing mature product lines than they do with more complex and profitable products that
could potentially drive future earnings. Contract manufacturers have responded by offering more sophistication in terms of design, materials and manufacturing capabilities, and the ability to manufacture more complex products.
THE OPERATOR’S DILEMMA

An Industry Built By Small Manufacturers
Small manufacturers formed the contract manufacturing industry, realizing they could provide a valuable service to OEMs. These manufacturers over time produced business for themselves by proving to OEMs that the manufacturing services they offered were often of a higher quality and lower cost than the OEM could do in-house. Several of these small manufacturing operations each independently provided a service to OEMs and gradually built their business up. As the industry has grown, these founders have since found themselves in the mix of hundreds of businesses like their own and much larger businesses trying to capitalize on the growth in the industry.

Existing contract manufacturers currently operate in an industry experiencing volatility due to the rapidly evolving medical device outsourcing market. OEMs have become more comfortable using contract manufacturing and now demand additional capabilities from these manufacturers. The business operators in this space are trying to manage a number of forces pulling their business in several directions. Not only do they face a rapidly growing market that demands new services, but they face increased competition and customers who are looking to manage fewer suppliers. Remaining competitive in today’s market involves either providing a superior service or product, or offering a broader package of solutions. Contract manufacturers are responding to these pressures by expanding their businesses through either acquisitions or investing capital to provide the additional capacity and capabilities required by OEMs.

NICHE MANUFACTURING
Smaller contract manufacturers who have either situated themselves within a niche area of the industry, developed strong relationships with customers, or possess proprietary technology or patents, that allow them to challenge larger competitors are in a strong position. In this rapidly growing market with consolidation occurring, one way smaller players can remain competitive is by investing and developing one particular niche and remaining the best in class at providing that particular service or product. Even though some competitors may offer a broader range of services, their niche solution is unique enough in the eyes of the OEMs to ensure that the solution is incorporated into outsourcing projects. This niche strategy has the added benefit of making the company an attractive target for a larger acquirer who lacks their specific capability.
Small Manufacturers Need to Think Strategically

Spending some time thinking strategically about where to focus can be invaluable for a small contract manufacturer. There are numerous factors to consider such as: the geographic proximity of the company to its customers, and the location of other potential customers, or where the large device firms are lacking, in order to provide a service or product that could be invaluable. If the company’s solution is labor intensive, think seriously about offshore operations, which are becoming more of a necessity to remain cost competitive in today’s manufacturing marketplace.

FULL-SERVICE MANUFACTURING

For companies that do not have a well protected niche or for companies that seek to take full advantage of the consolidation opportunity, a movement to provide a broader range of services is a strategy that deserves consideration. As OEMs seek to employ outsourcing for a great number of operations and reduce the number of suppliers, they are seeking firms who can perform a broad range of activities.

Becoming a full service provider is not without its challenges; a major issue facing smaller businesses looking to expand their operations is access to the resources necessary for growth. The medical device contract manufacturing segment is capital intensive, relying on large equipment and infrastructure resources to increase capacity. As a consequence, smaller businesses need to be creative in order to have access to expansion capital.

A small contract manufacturing company with extra cash on its balance sheet or additional debt capacity can pursue an acquisition strategy, as the players with the most market share in this arena have done. By identifying smaller companies that can provide complementary services or customers, a company can strategically grow itself through acquisition to become a bigger player.

For some companies to achieve their strategic goals, it makes sense to pursue a partnership with a financial sponsor, or a larger strategic partner, in order to either focus on a specific niche or expand the business. Sources of capital can come in several different forms:

1. *Commercial Banks.* Banks will offer some financing based on cash flow and tangible assets. Unless the existing business is large, they are not likely to support an acquisition strategy or offer unsecured debt.

2. *Private Equity Firms.* Private equity firms can offer substantial amounts of capital to grow the business or pursue an acquisition strategy and offer management expertise. These firms provide capital based on the growth opportunities for the business.

3. *Customers/Corporate Partners.* Corporate partners will provide capital related to specific projects or ventures to ensure a stable supply or partner exclusivity. Generally, they will not fund an acquisition strategy.
The right partnership can yield a range of benefits such as:

1. **Access to Capital.** Small businesses often identify areas for growth within their industry, but lack the ability to capitalize on these opportunities due to the lack of resources. Partnering with an entity that can provide necessary capital allows smaller contract manufacturers to make the investments that are necessary for their growth.

2. **Risk Reduction.** Investing more capital in a business involves taking a risk that many small business owners are unwilling to make when most of their net worth is already tied up in the business. Owners of small contract manufacturing business may identify potential areas for growth and have the resources to capitalize on those opportunities, but might be unwilling to place all of their eggs in one basket. Partnering with an entity with access to larger capital resources can allow them to avoid the risk of investing additional resources, but still allow them to capitalize on growth opportunities.

3. **Strengthen Management Team.** The typical contract manufacturer also lacks the management expertise possessed by larger entities. “Typical” contract manufacturing managers are generally heavily focused on the manufacturing side of business and tend to not allocate enough time to managing the growth of their business. Larger entities have the resources to dedicate personnel to thinking strategically about the business.

4. **Attractive Exit Opportunities.** Exit opportunities in the contract manufacturing industry are currently very attractive due to the strong interest in the sector by the private equity community and strategic players. Private equity has developed a particular interest in the contract manufacturing industry and several firms are attempting to consolidate the highly fragmented market. Larger companies are looking for ways to lower their manufacturing costs and also for new technologies that complement the production of their existing products and services. This strong interest has created a long list of buyers in the market providing sellers with a number of exit opportunities.

5. **Strong Valuation.** Private equity has recognized the profitability of consolidating the contract manufacturing industry and is therefore willing to pay unusually high multiples. As private equity consolidates small niche players in contract manufacturing they are able to create synergies among their portfolio companies, which allow them to pay more for acquisition candidates.
CONCLUSION

The rapidly growing and highly fragmented medical device contract manufacturing industry provides numerous opportunities for existing players and new entrants. The contract manufacturing industry is heavily dependent on the success of the overall medical device industry, which is expected to experience solid growth over the next five years. Not only do contract manufacturers depend on the health of the overall medical device industry, but also their ability to convince OEMs to substitute their manufacturing operations with those of an outsourced manufacturer. Healthcare payers are pressuring OEMs to keep costs low, which can be achieved by minimizing manufacturing costs through outsourcing. As a result of contract manufacturers proving their ability to provide reliable and consistent services, OEMs have begun to embrace outsourcing. As outsourcing has gained acceptance, larger manufacturers are now offering OEMs an enhanced service by packaging several different services into a one-stop shop.

Participants in the outsourcing industry have recognized the benefit of consolidating services and several are actively expanding their capabilities by acquiring contract manufacturers that offer additional services. Given the current fragmentation in the industry, there is no shortage of targets for those looking to pursue consolidation strategies. While full service contract manufacturers will lead the industry in the future, niche players with proprietary technology or products will also continue to be in demand by OEMs, offering services that OEMs cannot replicate in-house. Over the next few years, as existing players merge, new players enter, and the range of outsourced solutions expands, the successful organizations will be the ones that embrace this dynamic environment by either adding additional capabilities and scale or aggressively defending their niche.
Important Disclaimer
The information herein is not intended to be an offer to buy or sell, or a solicitation of an offer to buy or sell, any securities and including any expression of opinion, has been obtained from or is based upon sources believed to be reliable but is not guaranteed as to accuracy or completeness although Covington Associates (“CA”) believes it to be clear, fair and not misleading. CA may from time to time act as advisor, broker or banker in relation to the securities, or derivatives thereof, of persons, firms, or entities mentioned in this document or be represented on the board of such persons, firms or entities. Employees of CA or individuals connected to them, other than the authors of this report, may from time to time have a position in or be holding any of the investments or related investments mentioned in this document. Each author of this report is not permitted to trade in or hold any of the investments or related investments which are the subject of this document. CA is under no obligation to disclose or take account of this document when advising or dealing with or for their customers. The views of CA reflected in this document are subject to change without notice. To the maximum extent possible at law, CA does not accept any liability whatsoever arising from the use of the material or information contained herein. This research document is not intended for use by or targeted at private customers. Should a private customer obtain a copy of this report they should not base their investment decisions solely on the basis of this document but must seek independent financial advice.