InfuSystem Holdings, Inc
Form 10-K/A
December 12, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C., 20549

FORM 10-K/A

(Amendment No. 2)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2015

OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 001-35020

INFUSYSTEM HOLDINGS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**20-3341405**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

31700 Research Park Drive

Madison Heights, Michigan 48071

(Address of Principal Executive Offices) (Zip Code)

Registrant s Telephone Number, including Area Code:

(248) 291-1210

Securities Registered Pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on which Registered**
Common Stock, par value $0.0001 per share	**NYSE MKT**

Securities Registered Pursuant to Section 12(g) of the Act:

None

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES NO

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES NO

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter periods as the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. YES NO

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES NO

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K/A or any amendment to this Form 10-K/A.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (check one)

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES NO

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The aggregate market value of the registrant s voting equity held by non-affiliates of the registrant, computed by reference to the price at which the common stock was last sold as of the last business day of the registrant s most recently completed second fiscal quarter, was $64,370,857. In determining the market value of the voting equity held by non-affiliates, securities of the registrant beneficially owned by directors and officers of the registrant have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes. The number of shares of the registrant s common stock outstanding as of February 29, 2016 was 22,541,890.

DOCUMENTS INCORPORATED BY REFERENCE

None.

EXPLANATORY NOTE

On November 1, 2016, the Audit Committee of the Board of Directors of InfuSystem Holdings, Inc. (the Company) concluded, after review and discussion with management, that the Company s audited financial statements for the fiscal year ended December 31, 2015, and the Company s unaudited financial statements for each of the fiscal quarters ended March 31, 2015 through June 30, 2016 (collectively, the Financial Statements) should no longer be relied upon. This Amendment No. 2 to the Company s Annual Report on Form 10-K (this Second Form 10-K/A) for the fiscal year ended December 31, 2015, which was filed with the U.S. Securities and Exchange Commission (SEC) on March 9, 2016 (the Initial Form 10-K), as amended by Amendment No. 1 on Form 10-K/A to the Initial Form 10-K filed with the SEC on April 28, 2016 (the First Form 10-K/A and, together with the Initial Form 10-K, the Original Form 10-K), restates the Company s consolidated financial statements as of and for the fiscal year ended December 31, 2015, and amend the related notes and disclosures thereto, including the Company s controls and procedures. The impact on the Company s financial statements for the fiscal year ended December 31, 2015 and each of the fiscal quarters therein is to increase the provision for contractual allowance (thereby reducing accounts receivable as shown on the balance sheet) and other items by an aggregate cumulative amount of approximately $1.6 million for the year ended December 31, 2015 as follows:

(in thousands)	**March 31, 2015**	**June 30, 2015**	**September 30, 2015**	**December 31, 2015**	**Total 2015**
Unaudited quarterly impact	$ 173	$ 234	$ 381	$ 796	$ 1,584

The impact of these amounts are included in the following items on the Company s consolidated financial statements for the fiscal year ended December 31, 2015 and each of the fiscal quarters therein:

Consolidated Balance Sheet:	Consolidated Statement of Operations:
Accounts receivable, net	Rental revenues
Current assets	Net revenues
Deferred income taxes	Gross profit
Total assets	Operating income
Retained deficit	Income before income taxes
Total stockholders equity	Income tax (expense) benefit
Total liabilities and stockholders equity	Net income
	Net income per basic and diluted share

See the Company s Current Report on Form 8-K filed with the SEC on November 7, 2016 for additional details.

The items amended in the Original Form 10-K are listed under Items Amended by this Filing below. Other than the Items Amended by this Filing , disclosures in the Original Form 10-K remain unchanged. However, for the convenience of the reader, this Second Form 10-K/A restates in its entirety, as amended, the Company s Original Form 10-K. The Company has not modified or updated disclosures presented in the Original Form 10-K, except as required to reflect the effects of the restatement. Accordingly, this Second Form 10-K/A does not reflect events occurring after the filing of the Original Form 10-K and no attempt has been made in this Second Form 10-K/A to modify or update other disclosures as presented in the Original Form 10-K, except as specifically referenced herein. Accordingly, this Second Form 10-K/A should be read in conjunction with the Company s filings with the SEC subsequent to the filing of the Original Form 10-K.

Background of Restatement

The calculation error affects only the Company s rentals of infusion pumps to patients, which are paid for by third-party insurance payors. Revenue resulting from sales, service and rentals directly billed to health care providers is not impacted by this calculation error.

A summary of the restatement and its effects to the Company s consolidated financial statements for the fiscal year ended December 31, 2015 and each of the fiscal quarters therein, included within this Second Form 10-K/A, is presented in Note 3 in the accompanying notes to consolidated financial statements.

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Internal Control Over Financial Reporting

Under the supervision and with the participation of the Company s Chief Executive Officer (CEO) and Chief Financial Officer (CFO), management conducted a reassessment of the effectiveness of the Company s internal control over financial reporting as of December 31, 2015. The reassessment was based on criteria established in the framework Internal Control - Integrated Framework (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its evaluation, management concluded that the Company s internal control over financial reporting was not effective as of December 31, 2015 for the Company s estimated receivables collection methodology and its impact on the contractual allowance. The Company did not maintain an effective control environment to allow for the accurate review and filing of the Company s financial statements primarily attributable to the following factors:

- The Company did not have adequate processes or policies in place to enable members of its management team to timely review the Company s detailed calculation of accounts receivable collections and contractual allowance reserves;

- The Company did not have controls designed to validate the completeness and accuracy of underlying data used in the contractual allowance account reconciliation and in the determination of this significant estimate and, as a result, material errors were later identified in the underlying calculation used to support this significant estimate; and

- The Company did not have an adequate process or appropriate controls in place to support the accurate reporting of our financial results and disclosures on the Company s Form 10-K.

For a description of the material weakness in our internal controls over financial reporting and actions to be taken to remediate the material weakness, see Part II Item 9A Controls and Procedures.

Items Amended by this Filing

The following items included in the Original Form 10-K and First Form 10-K/A are amended by this Second Form 10-K/A:

- Part I, Item 1, Business;

- Part I, Item 1A, Risk Factors;

- Part II, Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations;

- Part II, Item 8, Financial Statements and Supplementary Data;

Part II, Item 9A, Controls and Procedures; and

Part IV, Item 15, Exhibits, Financial Statement Schedules.

As required by Rule 12b-15 under the Securities Exchange Act of 1934, as amended, new certifications by our principal executive officer and principal financial officer are filed as exhibits 31.1, 31.2, 32.1 and 32.2 to this Second Form 10-K/A.

The Company is concurrently filing amended Quarterly Reports on Form 10-Q/A for the fiscal quarters ended March 31, 2016 and June 30, 2016 and also on Form 10-Q for the fiscal quarter ended September 30, 2016 (for the three and nine months ended September 30, 2015 only) to reflect the effects of the restatement therein.

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Cautionary Statement About Forward-Looking Statements

Certain statements contained in this Second Form 10-K/A are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act) and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). The words believe, may, will, estimate, continue, a intend, should, plan, expect, strategy, future, likely, variations of such words, and other similar expression relate to the Company, are intended to identify forward-looking statements. However, the absence of these words or similar expressions does not mean that a statement is not forward-looking. In connection with the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, the Company is identifying certain factors that could cause actual results to differ, perhaps materially, from those indicated by these forward-looking statements. InfuSystem does not intend, and does not undertake any obligation to update any forward looking statement to reflect future events or circumstances after the date of such statements. Important factors that could cause our actual results and financial condition to differ materially from the forward-looking statements include, without limitation, those described in Risk Factors and elsewhere in this Second Form 10-K/A, and the following:

- our expectations regarding financial condition or results of operations in future periods;
- our expectations regarding enacted and potential legislative and regulatory changes impacting, among other things, the level of reimbursement received from the Medicare and state Medicaid programs including CMS competitive bidding;
- changes in third-party reimbursement processes, rates, contractual relationships and payor mix;
- our expectation of continued sales of products and competition for sales;
- our expectations regarding the size and growth of the market for our products and services;
- our ability to execute our business strategies to grow our business, including our ability to introduce new products and services;
- our ability to protect our intellectual property;
- our ability to execute on acquisition and joint-venture opportunities and integrate any acquired businesses;

our ability to implement, both internally and externally, information technology improvements and to respond to technological changes, interruptions and security breaches;

our ability to hire and retain key employees;

our ability to acquire pumps;

our ability to remain in compliance with our credit facility;

our dependence on our Medicare Supplier Number;

availability of chemotherapy drugs used in our infusion pump systems;

periodic reviews and billing audits from governmental and private payors;

physicians acceptance of infusion pump therapy over alternative therapies and focus on early detection and diagnostics;

our dependence on a limited number of third-party payors;

our ability to maintain relationships with health care professionals and organizations;

our ability to maintain controls and processes over billing and collecting and the adequacy of our allowance for doubtful accounts;

our ability to comply with changing health care regulations;

sequestration;

litigation in which we may be involved from time to time;

defective products manufactured by third-party suppliers;

natural disasters affecting us, our customers or our suppliers;

industry competition;

dependence upon our suppliers; and

general economic uncertainty.

These risks are not exhaustive. Other sections of this Second Form 10-K/A include additional factors which could adversely impact our business and financial performance. Moreover, we operate in a very competitive and changing environment. New risk factors emerge from time to time and it is not possible for us to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. All forward-looking statements made in this Second Form 10-K/A speak only as of the date of this report. We do not intend, and do not undertake any obligation, to update any forward-looking statements to reflect future events or circumstances after the date of such statements, except as required by law.

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You should not rely upon forward-looking statements as predictions of future events. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. We qualify all of our forward-looking statements by these cautionary statements. Although we believe that the expectations reflected in the forward looking-statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Therefore, you should not rely on any of the forward-looking statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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PART I

Item 1. Business.

Background

InfuSystem Holdings, Inc. (InfuSystem) is a Delaware corporation, formed in 2005. It operates through operating subsidiaries, including InfuSystem Holdings USA, Inc., a Delaware corporation (Holdings), InfuSystem, Inc., a California corporation (ISI), First Biomedical, Inc., a Kansas corporation (First Biomedical) and IFC, LLC, a Delaware limited liability company (IFC).

Business Concept and Strategy

We are a leading provider of infusion pumps and related products and services for patients in the home, oncology clinics, ambulatory surgery centers, and other sites of care from five locations in the United States and Canada. We provide our products and services to hospitals, oncology practices and facilities and other alternate site health care providers. Headquartered in Madison Heights, Michigan, we deliver local, field-based customer support, and also operate pump service and repair Centers of Excellence in Michigan, Kansas, California, Texas, Georgia and Ontario, Canada. ISI is accredited by the Community Health Accreditation Program (CHAP) while First Biomedical is ISO certified.

Our core service is to supply electronic ambulatory infusion pumps and associated disposable supply kits to oncology clinics, infusion clinics and hospital outpatient chemotherapy clinics to be utilized in the treatment of a variety of cancers including colorectal cancer, pain management and other disease states (Oncology Business). Colorectal cancer is the third most prevalent form of cancer in the United States, according to the American Cancer Society, and the standard of care for the treatment of colorectal cancer relies upon continuous chemotherapy infusions delivered via ambulatory infusion pumps.

In addition, we sell or rent new and pre-owned pole mounted and ambulatory infusion pumps to, and provide biomedical recertification, maintenance and repair services for oncology practices as well as other alternate site settings including home care and home infusion providers, skilled nursing facilities, pain centers and others. We also provide these products and services to customers in the hospital market.

We purchase new and pre-owned pole mounted and ambulatory infusion pumps from a variety of sources on a non-exclusive basis. We repair, refurbish and provide biomedical certification for the devices as needed. The pumps are then available for sale, rental or to be used within our ambulatory infusion pump management service.

One aspect of our business strategy is to expand into treatment of other cancers. In 2015, our Oncology Business approximated 70% of our total revenues. In 2015, we generated approximately 48% of our total revenues from treatments for colorectal cancer and 22% of our revenues from treatments for non-colorectal disease states. There are a number of approved treatment protocols for pancreatic, head and neck, esophageal and other cancers, as well as other disease states which present opportunities for growth. There are also a number of other drugs currently approved by the U.S. Food and Drug Administration (the FDA), as well as agents in the pharmaceutical development pipeline, which we believe could potentially be used with continuous infusion protocols for the treatment of diseases other than colorectal cancer. Additional drugs or protocols currently in clinical trials may also obtain regulatory approval over the next several years. If these new drugs or protocols obtain regulatory approval for use with continuous infusion protocols, we expect the pharmaceutical companies to focus their sales and marketing efforts on promoting the new

drugs and protocols to physicians.

Another aspect of our business is to seek opportunities to leverage our extensive billing capabilities, pump resources and networks of oncology practices and insurers. This leverage may take the form of new products and/or services, strategic alliances, joint ventures and/or acquisitions. One of these is providing our ambulatory pumps, products, and services in the area of post-surgical peripheral nerve block. With regard to acquisitions, we believe there are additional opportunities, beyond our acquisition of Ciscura Holding Company, Inc., and its subsidiaries (Ciscura) that was made in April 2015, to acquire smaller, regional competitors, in whole or part that perform similar services to us but do not have the national market access, network of third-party payor contracts or operating economies of scale that we currently enjoy. We also plan to leverage our extensive networks of oncology practices and insurers by distributing complementary products, including pain management and smart pumps, and introducing key new information technology based services such as BlockPain Dashboard™, EXPRESS™, InfuBus™ or InfuConnect™, InfuTrack™ and Pump Portal™.

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We face the risk that other competitors can provide the same services as we provide. That risk is currently mitigated and barriers to entry are created by our (i) growing number of third-party payor networks under contract, which exceeded 340 third-party payor networks for the fiscal year ended December 31, 2015; (ii) economies of scale, which allow for predictable reimbursement and less costly purchase and management of the pumps, respectively; (iii) established, long standing relationships as a provider of pumps to outpatient oncology practices in the U.S.; (iv) established national presence with Accountable Care Organizations (ACOs); (v) pump fleet of ambulatory and large volume infusion pumps for rent and for sale, which may allow us to be more responsive to the needs of physicians, outpatient oncology practices, hospitals, outpatient surgery centers, homecare practices, patient rehabilitation centers and patients than a new market entrant; (vi) six geographic locations in the U.S. and Canada that allow for same day or next day delivery of pumps with plans for a seventh in the northeastern U.S.; and (vii) pump repair and service capabilities at all of these facilities. We do not perform any research and development on pumps, but we have made, and continue to make, significant investments in developing our information technology as described below.

Management is intent on extending its considerable breadth of payor networks under contract as patients move into different insurance coverages, including Medicaid and Insurance Marketplace products. In some cases, this may slightly reduce our aggregate billed revenues payment rate but result in an overall increase in collected revenues, as shown by a reduction in bad debt expense. Consequently, we are increasingly focused on net collected revenues less bad debt.

In the midst of changes in the healthcare arena, we believe that we will support our overall business strategy discussed above by (i) focusing on supporting recurring revenues by increasing our pump fleet; (ii) improving liquidity and strengthening the balance sheet by keeping debt levels comparable to our operations; (iii) improving internal operational efficiencies; (iv) increasing our product and services offerings; (v) enhancing our technology offerings to the patients and providers of care; and (vi) investigating synergistic acquisitions.

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Continuous Infusion Therapy

Continuous infusion of chemotherapy involves the gradual administration of a drug via a small, lightweight, portable infusion pump over a prolonged period of time. A cancer patient can receive his or her medicine anywhere from one to 30 days per month depending on the chemotherapy regimen that is most appropriate to that individual s health status and disease state. This may be followed by periods of rest and then repeated cycles with treatment goals of progression-free disease survival. This drug administration method has replaced intravenous push or bolus administration in specific circumstances. The advantages of slow continuous low doses of certain drugs are well documented. Clinical studies support the use of continuous infusion chemotherapy for decreased toxicity without loss of anti-tumor efficacy. The 2015 National Comprehensive Cancer Network (NCCN) Guidelines recommend the use of continuous infusion for treatment of numerous cancer diagnoses. We believe that the growth of continuous infusion therapy is driven by three factors: evidence of improved clinical outcomes; lower toxicity and side effects; and a favorable reimbursement environment.

Significant recent progress has been made in the treatment of colorectal cancer due to advances in surgery, radiotherapy and chemotherapy. In the late 1990s, medical researchers discovered that the delivery method of the drug (or schedule) was a key component to drug availability, efficacy and tolerability. Schedule dependent anti-tumor activity and toxicity has resulted in continuous infusion 5-Fluorouracil being adopted as the standard of care. In 2000, the FDA approved Camptosar (the trade name for the generic chemotherapy drug Irinotecan), a drug developed by Pfizer, for first-line therapy in combination with 5-Fluorouracil for the treatment of colorectal cancer. In 2002, the FDA approved Eloxatin (the trade name for the generic chemotherapy drug Oxaliplatin), a drug developed by Sanofi-Aventis, for use in combination with continuous infusion 5-Fluorouracil for the treatment of colorectal cancer. FOLFIRI, the chemotherapy protocol which includes Camptosar in combination with continuous infusion 5-Fluorouracil and the drug Leucovorin, and FOLFOX, the chemotherapy protocol which includes Eloxatin in combination with continuous infusion 5-Fluorouracil and Leucovorin, have resulted in significantly improved overall survival rates for colorectal cancer patients at various stages of the disease state. We believe that Sanofi-Aventis and Pfizer have each dedicated significant resources to educating physicians and promoting the use of FOLFOX and FOLFIRI. Simultaneously, the NCCN has established these regimens as the standards of care for the treatment of colorectal cancer.

The use of continuous infusion has been demonstrated to decrease or alter the toxicity of a number of cytotoxic, or cell killing agents. Higher doses of drugs can be infused over longer periods of time, leading to improved tolerance and decreased toxicity. For example, the cardiotoxicity (heart muscle damage) of the chemotherapy drug Doxorubicin is decreased by schedules of administration according to The Chemotherapy Source Book by Michael C. Perry. Nausea, vomiting, diarrhea and decreased white blood cell and platelet counts are all affected by duration of delivery. Continuous infusion can lead to improved tolerance and patient comfort while enhancing the patient s ability to remain on the chemotherapy regimen. Additionally, the lower toxicity profile and resulting reduction in side effects enables patients undergoing continuous infusion therapy to continue a relatively normal lifestyle, which may include continuing to work, going shopping, and caring for family members. We believe that the partnering of physician management and patient autonomy provide for the highest quality of care with the greatest patient satisfaction.

We believe that oncology practices have a heightened sensitivity to whether and how much they are reimbursed for services. Simultaneously, the Center for Medicare and Medicaid Services (CMS) and private insurers are increasingly focusing on evidence-based medicine to inform their reimbursement decisions that is, aligning reimbursement with clinical outcomes and adherence to standards of care. Continuous infusion therapy is a main component of the standard of care for certain cancer types because clinical evidence demonstrates superior outcomes. Payors recognize this and it is reflected in favorable reimbursement for clinical services related to the delivery of this care.

Services

Our core service is our Oncology Business. After providing ambulatory pumps to oncology offices, infusion clinics and hospital and outpatient chemotherapy clinics, we then directly bill and collect payment from payors and patients for the use of these pumps. At any given time, our pumps are in the possession of these facilities, on a patient, in transport, or in our facilities for cleaning, calibration and storage as reserves for increased demand.

After a physician determines that a patient is eligible for ambulatory infusion pump therapy, the physician arranges for the patient to receive an infusion pump and provides the necessary chemotherapy drugs. The physician and nursing staff train the patient in the use of the pump and initiate service. The physician bills the payors, which include Medicare, Medicaid, third-party payor companies or patients for the physician s professional services associated with initiating and supervising the infusion pump administration, as well as the supply of drugs. We directly bill (i) payors and (ii) patients for copays and deductibles, for the use of the pump and related disposable supplies. Billing to payors requires coordination with patients and physicians who initiate the service, as physicians offices must provide us with appropriate documentation (patient s insurance information, physician s order, an

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acknowledgement of benefits that shows receipt of equipment by the patient, and, in some cases, physician s progress notes) in order for us to submit a bill to the payors. We do provide assistance to those that cannot afford our pumps via our financial hardship program a program that usually matches what our physician practices provide as long as the uninsured patients meet certain criteria. This billing process is handled from our Madison Heights, Michigan location.

In addition to providing high quality and convenient care, we believe that our business offers significant economic benefits for patients, providers and payors.

We provide patients with 24-hour by 7 days a week (24x7) service and support. We employ oncology, pain, and Intravenous Certified and Oncology Certified registered nurses trained on ambulatory infusion pump equipment who staff our 24x7 hotline to address questions that patients may have about their pump treatment, the infusion pumps or other medical or technical questions related to the pumps.

Physicians use our services to outsource the capital commitment, pump service, maintenance and billing and administrative burdens associated with pump ownership. Our services also allow the doctor to continue a direct relationship with the patient and to receive professional service fees for setting up the treatment and administering the drugs.

We provide methods for the physician offices to deliver the appropriate paperwork for billing through a number of electronic means including EXPRESS™ and InfuConnect™ reducing the required effort on the employees of the physician offices.

We believe our services are attractive to payors because such services are generally less expensive than hospitalization or home care.

Other services we offer include the rental, sale or leasing of pole mounted and ambulatory infusion pumps to oncology practices, hospitals and other clinical settings. As of December 31, 2015, our rental fleet of pole mounted and ambulatory pumps had a historical cost of $53.7 million, up from $43.2 million from the end of 2014, and included approximately 70 makes and models of equipment dedicated to our rental services. These pumps are available for daily, weekly, monthly or annual rental periods. As of December 31, 2015 and 2014, we had a fleet of new and used pole mounted and ambulatory pumps with a historical cost of $2.3 million for sale or lease.

In addition to sales, rental and leasing services, we also provide biomedical maintenance, repair and certification services for the devices we offer as well as for devices owned by customers but not acquired from us. We operate pump service and repair Centers of Excellence from all of our locations across the United States and Canada and employ a staff of highly trained technicians to provide these services. Our main Center of Excellence for service is our Lenexa, Kansas facility.

We also offer electronic ambulatory infusion pumps for post-operative pain management using our pumps along with a numbing agent and a continuous nerve block catheter continuous peripheral nerve block (CPNB). Using CPNB for the management of post-operative pain, which usually lasts two to three days after surgery, can result in reduced pain for the patient, increased satisfaction scores for the surgical center or hospital, and reduced need for post-operative medication.

Information Technology

The Company s first Chief Information Officer was hired in 2013 to transform the Company s Information Technology (IT) platform and enhance business processes beginning in 2014. IT refocused on not only supporting our internal IT needs to reduce our platforms and redundant systems from two IT platforms into a consolidated solution but also in supporting electronic medical record technology (EMR) to be used by medical facilities using the Company s infusion pumps and services via our solutions such as EXPRESS™ and InfuConnect™. This focus has enabled current billing information to be transferred to the Company from these facilities electronically and automatically, bypassing the current methods of mail, email, and/or facsimile. We expect that this new focus will continue to strengthen our relationships with our existing customers and result in additional investment in intangible software assets by the Company. Additional IT customer focused solutions are PumpPortal™, InfuTrack™ (Pump Fleet Lifecycle Management Solutions) and BlockPain Dashboard™. Our continued focus on IT efforts has resulted in the following new products:

EXPRESS™, powered by InfuBus data integration platform, provides for paperless delivery of the appropriate information for InfuSystem to bill payors:

- eliminating all paper;
- providing an enhanced visibility as a result of real time status and reporting;
- reducing risk of error;
- automating treatment logs, pump assignments, tracking and physician s orders;

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providing a secure scanner for easy pumps assignment to patients; and

removing interruptions from physician practices daily schedules, and standardizing data flow for clinics and hospitals with multiple locations

Pump Fleet Lifecycle Management Solutions, which provide interfaces for customers to keep their pump fleets right-sized and in good condition by:

scheduling service;

requesting a returned goods authorization;

approving price quotes;

printing shipping labels;

recertifying pumps annually;

accessing pump service and certification history;

tracking pumps by location;

accessing pump order and repair history; and

ordering rental pumps.

BlockPain Dashboard™, which supports our new product solutions in providing our ambulatory pumps, products, and services in the area of post-surgical peripheral nerve block by:

delivering patient real-time pain score reporting to the provider;

supporting high patient satisfaction; and

providing data online, anytime.

In 2015 and 2014, the Company capitalized in excess of $5.6 million and $3.4 million, respectively, into IT, with specific focus as discussed above, plus other internal operational efficiencies and new products and support.

Relationships with Physician Offices

As of December 31, 2015, we had business relationships with clinical oncologists in excess of 1,700 outpatient oncology clinics. Although this represents a substantial number of the oncologists in the United States, we believe we can continue to expand our network to further penetrate the oncology market. Based on our retention rates and the positive results of our professional customer satisfaction research, we believe our relationships with physician offices are strong.

We believe that, in general, we do not compete directly with hospitals and physician offices to treat patients. Rather, by providing products and services to hospitals and physician offices and other care facilities and providers, we believe that we assist other providers in meeting increasing patient demand and managing institutional constraints on capital and manpower due to the nature of limited resources in hospitals and physician offices.

Physician practices in the oncology field are consolidating similar to healthcare practices in general. However, as of December 31, 2015, we had gained more practices than we had lost due to consolidation. We expect this trend to continue in the near future.

Employees

As of December 31, 2015, we had 261 employees, including 242 full-time employees and 19 part-time or contract employees. None of our employees are unionized.

Material Suppliers

We supply a wide variety of pumps and associated equipment, as well as disposables and ancillary supplies. The majority of our pumps are electronic infusion pumps purchased from the following manufacturers, each of which supplies more than 10% of the ambulatory pumps purchased by us: Smiths Medical, Inc. and WalkMed Infusion, LLC. We have supply agreements in place with these suppliers. Certain spot purchases are made on the open market subject to individual negotiation.

Seasonality

Our business rental activity is not subject to seasonality. Revenues from this activity, net of bad debt, may be seasonal due to the impact of co-pays and deductibles for patients insurance that traditionally reset each January. This has been further impacted by

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changes in the insurance industry as it responds to increased government regulation. Also, rental customers tend to make buy versus rent decisions late in the year as customer capital budgets are being finalized, impacting sales revenue in the second half of the year, predominantly in the fourth quarter. Furthermore, as the Company s liquidity has improved, opportunistic pump purchases are made from time to time. These opportunistic pump purchases also allow for opportunistic pump sales, which could be material. The timing of such purchases and sales vary within the course of a year.

Environmental Laws

We are required to comply with applicable federal, state and local environmental laws regulating the disposal of cleaning agents used in the process of cleaning our ambulatory infusion pumps, as well as the disposal of sharps and blood products used in connection with the pumps. We do not believe that compliance with such laws has a material effect on our business.

Significant Customers

We have sought to establish contracts with as many third-party payor organizations as commercially practicable, in an effort to ensure that reimbursement is not a significant obstacle for providers who recommend continuous infusion therapy and wish to utilize our services. A third-party payor organization is a health care payor or a group of medical services payors that contracts to provide a wide variety of health care services to enrolled members through participating providers such as us. A payor is any entity that pays on behalf of a member patient.

As of December 31, 2015, we had contracts with more than 340 third-party payor networks under contract. Material terms of contracts with third-party payor organizations are typically a set fee or rate, or a discount from billed charges for equipment provided. The majority of these contracts generally provide for a term of one year, with automatic one-year renewals, unless we or the contracted payor elect not to renew. For 2015 and 2014, our largest contracted payor was Medicare, which accounted for approximately 32% and 30% of our net revenue from our Oncology Business for 2015 and 2014, respectively, and approximately 19% of our total revenues for both 2015 and 2014. Medicare represented 23% and 18% of our consolidated accounts receivable, net for the years ended December 31, 2015 and 2014, respectively. For 2015 and 2014, our next largest contracted payor, was a national association comprised of multiple members, which, in the aggregate, accounted for approximately 18% of our net revenue from our Oncology Business for both 2015 and 2014, and approximately 12% of our total revenues for both 2015 and 2014. This same contracted payor represented 31% and 26% of our consolidated accounts receivable, net for the years ended December 31, 2015 and 2014, respectively. We also contract with various other third-party payor organizations, Medicaid, commercial Medicare replacement plans, self-insured plans and numerous other insurance carriers. Other than the payors noted above, no other single payor represented more than 10% of third-party payor net revenue.

By 2016, CMS is required by regulation to begin the process of fully implementing some form of competitive bidding. On October 31, 2014, CMS released a final rule entitled, End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (Final Rule). This Final Rule was published in its entirety in the *Federal Register* on November 6, 2014 and finalizes several provisions related to durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) including:

- Items and services subject to competitive bidding pricing in 10 or fewer Competitive Bidding Areas (CBAs) will be subject to payment reductions where Single Payment Amounts (SPAs) will be equal to 110% of the unweighted average SPAs in those areas outside of the current CBAs.

This includes the category for external infusion pumps and supplies.

Such adjustments would apply in non-CBAs for items furnished on or after January 1, 2016. CMS has adopted a six-month phase-in of the adjustments to these payment amounts. For items and services with dates of service from January 1, 2016 through June 30, 2016, the fee schedule amounts in non-CBAs will be based on 50% of the un-adjusted fee schedule amount and 50% of the adjusted fee schedule amount. Beginning on July 1, 2016, the fully adjusted payment rates will apply.

In December 2015, CMS released the SPAs for 2016. These SPAs confirmed our interpretation of the Final Rule. Coupling the impact of competitive bidding with the impact of the addition of new payor networks associated with the Patient Protection and Affordable Care Act (the ACA) is complicated. Medicare Advantage plans managed by commercial payors and more Medicaid plans are now tied to CMS pricing. Increases in networks under contract have now increased our net collected revenues as more revenues are the responsibility of a third-party payor, as opposed to a patient which traditionally is associated with a higher rate of bad debt.

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Based on the mix and billing levels of revenues and fee schedules for the fiscal year ended December 31, 2015, we estimate when applying the Final Rule and the 2016 SPA s that our revenues could be reduced by up to approximately $3.8 million in 2016 and an additional $1.2 million in 2017, in each case, as compared to our revenue in 2015. These reductions are expected to be offset by an increase in revenues related to our increase in networks under contract by $1.5 million in 2016 and management believes further increases and improvements in its networks under contract can improve revenues in 2017, as well. The Company believes that its focus on growth in recurring revenues, improving its commercial contracts, revenues from new products and services, improvements in IT, and other operational improvements could also potentially offset these reductions.

Certain factors such as revenue mix, competitive responses, commercial and Medicaid contracts tied to CMS, and other potential factors, could impact these estimates. As a result, there can be no assurances as to the actual impact of the Final Rule and the 2016 SPA s in 2016 and 2017, which could negatively impact the Company s market share, negatively impact business with the Company s customers and other payors and significantly reduce revenues, earnings and cash flow beyond what is mentioned above.

Competitors

We believe that our competition is primarily composed of regional durable medical equipment (DME) providers, hospital-owned DME providers, physician providers and home care infusion providers. An estimate of the number of competitors is not known or reasonably available, due to the wide variety in type and size of the market participants described below. We are not aware of any industry reports with respect to the competitive market described below. The description of market segments and business activities within those market segments is based on our experiences in the industry.

Regional DME Providers: Regional DME providers act as distributors for a variety of medical products. We believe regional DME provider sales forces generally consist of a relatively small number of salespeople, usually covering several states. Regional DME providers tend to carry a limited selection of infusion pumps and their salespeople generally have limited resources. Regional DME providers usually do not have 24x7 nursing services. We believe that regional DME providers have relatively few third-party payor contracts, which may prevent these providers from being paid at acceptable levels and may also result in higher out-of-pocket costs for patients.

Hospital-owned DME Providers: Many hospitals have in-house DME providers to supply basic equipment. In general, however, these providers have limited capital and tend to stock a small inventory of infusion pumps. We believe that hospital-owned providers have limited ability to grow because of limited patient populations. Growth from outside of the hospital may pose a challenge because hospitals typically will not provide referrals to competitors, instead preferring to offer patients a choice of non-hospital-affiliated DME providers.

Physician Providers: A limited number of physicians maintain an inventory of their own infusion pumps and provide them to patients for a fee. However, we believe that pump utilization in this area tends to be low and the costs associated with ongoing supplies, preventative maintenance and repairs can be relatively high. Moreover, we believe that a high percentage of DME claims by doctors are rejected by payors upon first submission, requiring a physician s staff to spend significant time and effort to resubmit claims and receive

payment for treatment. The numerous service and technical questions from patients may present another significant cost to a physician provider s staff.

Home Care Infusion Providers: Home care infusion providers provide chemotherapy drugs and services to allow for in-home patient treatment. We believe that home care infusion treatment can be very costly and that many patients do not carry insurance coverage that covers home-based infusion services, resulting in larger out-of-pocket costs. Because home care treatments may take as long as six months, these costs can be high and can result in higher patient co-payments. We believe that home care providers may also be reluctant to offer 24x7 coverage or additional patient visits, due to capped fees.

Regulation of Our Business

Our business is subject to certain regulations. Specifically, as a Medicare supplier of DME and related supplies, we must comply with supplier standards established by CMS regulating Medicare suppliers of DMEPOS (DMEPOS Supplier Standards). The DMEPOS Supplier Standards consist of 30 requirements that must be met in order for a DMEPOS supplier to be eligible to receive payment for a Medicare-covered item. Some of the more significant DMEPOS Supplier Standards require us to (i) advise Medicare beneficiaries of their option to purchase certain equipment, (ii) honor all warranties under state law and not charge Medicare beneficiaries for the repair or replacement of equipment or for services covered under warranty, (iii) permit CMS agents to conduct on-site inspections to ascertain compliance with the DMEPOS Supplier Standards, (iv) maintain liability insurance in prescribed amounts, (v) refrain from contacting Medicare beneficiaries by telephone, except in certain limited circumstances, (vi) answer questions and respond to complaints of beneficiaries regarding the supplied equipment, (vii) disclose the DMEPOS Supplier Standards to each Medicare beneficiary to whom we supply equipment, (viii) maintain a complaint resolution procedure and record certain information regarding each complaint, (ix) maintain accreditation from a CMS approved accreditation organization, and (x) meet certain specified surety bond requirements.

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We are also subject to the provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which are designed to protect the security and confidentiality of certain patient health information. Under HIPAA, we must provide patients access to certain records and must notify patients of our use of personal medical information and patient privacy rights. Moreover, HIPAA sets limits on how we may use individually identifiable health information and prohibits the use of patient information for marketing purposes. The adoption of the American Recovery and Reinvestment Act of 2009 (ARRA) includes a new breach notification requirement that applies to breaches of unsecured health information occurring on or after September 23, 2009. We are subject to regulations in the various states in which we operate. We believe we are in material compliance with all such regulations.

The health care industry is undergoing fundamental changes resulting from political, economic and regulatory influences. In 2010, the ACA was enacted into law to reform the United States health care system and implemented in 2013. The legislation was intended to expand access to health insurance coverage, improve quality and reduce costs over time. We believe the law has impacted and will continue to impact various aspects of our business operations, including payor mix as our Medicaid and patient pay percentages increased in 2015 over 2014. However, it is unclear how the law will further impact reimbursement rates.

In addition, the ACA imposes a 2.3% excise tax on medical devices that applies to sales within the United States of a majority of our pump products that we purchase. This law imposes an excise tax on the first sale of medical devices by a manufacturer, producer, or importer equal to 2.3% of the sales price. This tax only applies directly to new pumps that we purchase from manufacturers. Taxable medical devices include any device as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act intended for humans, with the exception of eyeglasses, contact lenses, hearing aids and any other device determined by the Secretary of Health and Human Services to be a type which is generally purchased by the general public at retail for individual use. On December 18, 2015, under the Consolidated Appropriations Act, 2016 (Pub. L. 114-113), this excise tax was given a two year moratorium on the medical device excise tax by Section 4191 of the Internal Revenue Code (the Code). Thus, the medical device excess tax does not apply to the sale of a taxable medical device by the manufacturer, producer, or importer of the device during the period beginning on January 1, 2016 and ending on December 31, 2017. Future legislation could have a material effect on our business, cash flows, financial condition and results of operations.

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Recent Events in Our Business

CMS

On April 21, 2015 the CMS announced plans to recompete the supplier contracts awarded in Round 1 Recompete of the Medicare DMEPOS Competitive Bidding Program. CMS is required by law to recompete contracts under the DMEPOS Competitive Bidding Program at least once every three years. The Round 1 Recompete contract period for all product categories expires on December 31, 2016. The Round 1 2017 product categories do not include a category for external infusion pumps as in the previous Round 1 Recompete.

See the additional discussion above under Item 1 Business - Significant Customers.

Credit Facility

On March 23, 2015, we and our direct and indirect subsidiaries entered into the credit agreement (the Credit Agreement) with JPMorgan Chase Bank, N.A., as lender (the Lender). The Credit Agreement consists of a $27.0 million Term Loan A, up to $8.0 million Term Loan B and a $10.0 million revolving credit facility (the Revolver), all of which mature on March 23, 2020 (collectively, the Credit Facility).

Under the terms of the Credit Agreement, principal payments equal to $1.0 million are due on Term Loan A on the last business day of each quarter beginning with the last business day of September 2015 and are due until the maturity date of the Credit Facility. Principal payments on Term Loan B are due on the last business day of each fiscal quarter beginning with the last business day of March 2016. The value of each principal payment due on Term Loan B shall be equal to 3.575% of the principal balance of Term Loan B as of the Term Loan B Draw Expiration Date for the first eight quarterly payments. Thereafter, the next 8 principal payments shall be equal to 4.475% of the principal balance of Term Loan B as of the Term Loan B Draw Expiration Date. The entire outstanding balance of the revolver shall be due at the maturity of the Credit Facility.

During the year ended December 31, 2015, we made optional pre-payments of $4.8 million on our Term Loan A, which we can apply against future mandatory payments. Prepayments of $1.9 million were applied to the September 30, 2015 and December 31, 2015 Term Loan A required principal payments. Remaining prepayments of $2.9 million are available towards 2016 future mandatory payments.

Ciscura

On April 20, 2015 (the Closing Date), we closed on the acquisition of substantially all of the assets of Ciscura, a privately-held Southeastern regional provider of ambulatory infusion pumps and services to medical facilities based in Alpharetta, Georgia.

We acquired approximately 1,800 infusion pumps from Ciscura, its four-person field sales team, as well as its facilities management personnel, which have become the foundation of our new Southeast facility. With this new regional warehouse and service facility, we will be in close proximity to a number of our largest existing customers, in addition to new customers previously serviced by Ciscura, enabling same day service for equipment and supplies to much of the Southeast region.

The asset purchase agreement provided for an adjustment to the purchase price based on the final number of pumps acquired and the associated treatments, which were generated during the 90-day period post-closing from the approximately 100 medical facility relationships Ciscura had prior to the acquisition. The final total purchase price,

which was based on the number of acquired pumps and associated treatments, was approximately $6.2 million.

On the Closing Date, we made an initial payment of $3.8 million, an additional payment of $2.1 million was made in September 2015 and a final payment of $0.3 million was made in November 2015. The associated integration and transaction costs expended in 2015 were $0.7 million.

Available Information

Our Internet address is www.infusystem.com. On this Web site, we post the following filings as soon as reasonably practicable after they are electronically filed with or furnished to the U.S. Securities and Exchange Commission (the SEC): our Annual Reports on Form 10-K; amended Annual Reports on Form 10-K/A; our Quarterly Reports on Form 10-Q; our amended Quarterly Reports on Form 10-Q/A; our Current Reports on Form 8-K; our proxy statements related to our annual stockholders meetings; and any amendments to those reports or statements. All such filings are available on our Web site free of charge. The charters of our audit, nominating and governance and compensation committees and our Code of Business Conduct and Ethics Policy are also available on our Web site and in print to any stockholder who requests them. The content on our Web site is not incorporated by reference into this Second Form 10-K/A unless expressly noted.

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Item 1A. Risk Factors.

An investment in our securities involves a high degree of risk. You should consider carefully all of the material risks described below, together with the other information contained in this Second Form 10-K/A. If any of the following events occur, our business, financial condition, results of operations and cash flows may be materially adversely affected.

RISK FACTORS RELATING TO OUR BUSINESS AND THE INDUSTRY IN WHICH WE OPERATE

We have restated our prior consolidated financial statements, which may lead to additional risks and uncertainties, including loss of investor confidence, stockholder litigation and negative impacts on our stock price.

As discussed in Note 3 to our consolidated financial statements included in Item 8 of this Second Form 10-