
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

Form 10-K

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

For the Fiscal Year Ended June 30, 2015

OR

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

For the transition period from _____ to _____

Commission File Number 001-34540

UNILIFE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

27-1049354
(I.R.S. Employer
Identification No.)

250 Cross Farm Lane, York, Pennsylvania
(Address of principal executive offices)

17406
(Zip Code)

Registrant's telephone number, including area code (717) 384-3400

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 \$0.01 per share

The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:

None

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 Section 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that 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 Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) 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 (§ 229.405 of this chapter) 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 or any amendment to this Form 10-K. ☐

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 ☐ (Do not check if a smaller reporting company)

Smaller reporting company ☐

Indicated by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the common equity held by non-affiliates of the registrant as of December 31, 2014, the last business day of the registrant's most recently completed second fiscal quarter was \$339.5 million, computed by reference to the closing sale price of our common stock. For purposes of the foregoing calculation only, the registrant has assumed that all officers and directors of the registrant are affiliates.

As of September 4, 2015, there were 136,123,818 shares of our common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement to be filed with the Commission pursuant to Regulation 14A in connection with the registrant's 2015 Annual Meeting of Stockholders, to be filed subsequent to the date hereof, are incorporated by reference into Part III of this Report. Such Definitive Proxy Statement will be filed with the Securities and Exchange Commission not later than 120 days after the conclusion of the registrant's fiscal year ended June 30, 2015.

UNILIFE CORPORATION
FORM 10-K
FOR THE FISCAL YEAR ENDED JUNE 30, 2015

TABLE OF CONTENTS

PART I

Item 1.	Business	3
Item 1A.	Risk Factors	19
Item 1B.	Unresolved Staff Comments	35
Item 2.	Properties	35
Item 3.	Legal Proceedings	35
Item 4.	Mine Safety Disclosures	36

PART II

Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	37
Item 6.	Selected Financial Data	39
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations . .	40
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	53
Item 8.	Financial Statements and Supplementary Data	55
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure . .	92
Item 9A.	Controls and Procedures	92
Item 9B.	Other Information	93

PART III

Item 10.	Directors, Executive Officers and Corporate Governance	94
Item 11.	Executive Compensation	94
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	94
Item 13.	Certain Relationships and Related Transactions, and Director Independence	105
Item 14.	Principal Accounting Fees and Services	105

PART IV

Item 15.	Exhibits and Financial Statement Schedules	106
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Presentation of Information

References to the “Company”, “we”, “our” or “us” include Unilife Corporation and its consolidated subsidiaries, including Unilife Medical Solutions Limited, or UMSL, unless the context otherwise requires. References to “Unilife” are references solely to Unilife Corporation.

Trademarks, Trade Names and Service Marks

UNILIFE®, UNIFILL®, UNITRACT®, UNIFILL FINESSE®, RITA®, PRECISION-THERAPY®, FLEX-THERAPY®, EZMIX®, OCU-JECT®, DEPOT-JECT®, MICRO-JECT®, and OCU-MIX® are registered trademarks of the Company in the United States and in many international jurisdictions. UNIFILL ALLURE™, UNIFILL NEXUS™, UNIFILL SELECT™, EZMIX GENESIS™, EZMIX PRODIGY™, EZMIX ENGAGE™, IMPERIUM™, LISA™, AUTOMIX PRESTO™, READYTOGO™, and FLEXWEAR™ are common law trademarks of the Company in the United States and in many international jurisdictions. All trademarks, trade names or service marks referred to in this Annual Report on Form 10-K are the property of the Company unless otherwise indicated.

Cautionary Note Regarding Forward-Looking Information

This Annual Report on Form 10-K contains forward-looking statements. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements. The forward-looking statements are contained principally in the sections entitled “Business,” “Risk Factors,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “predicts,” “potential” and similar expressions intended to identify forward-looking statements. These forward-looking statements include statements about the following:

- our ability to obtain additional funding to continue our operations and pay our expenses;
- our ability to complete a transaction which would enhance shareholder value as a result of our exploration of strategic alternatives;
- our ability to develop and achieve substantial sales of our products to our customers;
- legal and regulatory requirements and developments in the U.S. and foreign countries;
- the clinical development, therapeutic efficacy and market acceptance of our customers’ product candidates;
- the ability to satisfy our debt obligations and comply with our restrictive covenants;
- existing, recently enacted and future legislation and reimbursement practices regarding the healthcare system;
- our financial performance;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to continue as a going concern for the next 12 months;
- the success of competing products that are or become available;
- obtaining and maintaining intellectual property protection for our technology and products;
- our ability to maintain and perform under our customer agreements;
- our exposure to manufacturing and other business disruptions;
- our ability to limit our exposure to product liability lawsuits;
- our ability to successfully manage our growth;

- our exposure to scrutiny and increased expenses as a result of being a public company;
- the impact on the cost and availability of raw materials and certain components due to potential supply changes;
- our ability to maintain and protect our information technology systems; and
- our failure to recruit or retain key personnel or to retain our executive officers.

These forward-looking statements are based on management's beliefs and assumptions and on information currently available to our management. However, you should not place undue reliance on any such forward-looking statements because such statements speak only as of the date when made. We do not undertake any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. In addition, forward-looking statements are subject to certain risks and uncertainties that could cause actual results, events and developments to differ materially from our historical experience and our present expectations or projections. These risks and uncertainties include, but are not limited to, those described in "Item 1A. Risk Factors" and elsewhere in this Annual Report on Form 10-K and those that may be described from time to time in our future reports that we file with the Securities and Exchange Commission. You should read completely this Annual Report on Form 10-K, the documents that we have filed as exhibits to this Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K. The forward-looking statements contained in this Annual Report on Form 10-K are subject to the safe-harbor protection provided by the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act.

PART I

Item 1. Business

Company Background

We are a designer, manufacturer and supplier of innovative injectable drug delivery systems that can enhance and differentiate the injectable drugs, biologics and vaccines, or collectively, injectable therapies, of our pharmaceutical and biotechnology customers. We have a broad portfolio of proprietary product platforms, including pre-filled syringes, wearable injectors, insulin delivery systems, disposable and reusable auto-injectors, drug reconstitution delivery systems, ocular delivery systems and other systems for the targeted delivery of injectable therapies. Products within each platform are differentiated from conventional products, with innovative features and functionality designed to optimize the safe, simple and convenient administration of an injectable therapy. The majority of our products are designed for sale directly to pharmaceutical and biotechnology companies who are expected to supply them as drug-device combination products, pre-filled and ready for administration by end-users, such as health-care providers or patients. Other of our products, like our reusable auto-injectors and certain systems for targeted drug delivery, are designed to either be sold to pharmaceutical or biotechnology companies for use as combination products or to be sold directly by us to a health care provider or end user without having the device pre-filled by a pharmaceutical company. Products within each of our platforms can be customized by us to address specific customer, therapy, patient and/or commercial requirements.

Our growing base of customers includes Sanofi S.A., or Sanofi, MedImmune LLC, or MedImmune, AbbVie Inc., or AbbVie, Novartis International AG, or Novartis, and Hikma Pharmaceuticals PLC, or Hikma. In addition to the filling, assembly and/or packaging of our products with injectable therapies, our customers are also, with respect to most of our products, responsible for the regulatory approval, sale and marketing of their final drug-device combination products. Where we sell our products directly to healthcare providers or end users without having them pre-filled by a pharmaceutical or biotechnology company, we would be responsible for the regulatory approval, sale and marketing of the final device. In addition to product sales, we can generate revenue from customization programs, upfront fees and exclusivity or royalty payments.

We are a Pennsylvania-based and Delaware-incorporated business since 2009, and began operations in Australia in 2002.

Our Business

We build long-term relationships with pharmaceutical and biotechnology companies in which we design, manufacture and supply them with innovative injectable drug delivery systems that can be used to enhance and differentiate their injectable therapies. An injectable drug delivery system is a product that forms a part of a drug-device combination product that is utilized by a pharmaceutical or biotechnology company to facilitate the administration of a measured dose of an injectable therapy by end-users. Examples of injectable drug delivery systems include pre-filled syringes, which serve as both the primary drug container and administration system for an injectable therapy, and auto-injectors that allow patients to automatically self-administer the contents of a pre-filled syringe without seeing a needle.

We believe our portfolio of injectable drug delivery systems is the most extensive and customer-centric in our industry, and can accommodate the needs of most injectable therapies. While our proprietary products are designed with innovative features and functionality, they utilize standard materials to support drug compatibility, and can be supplied to customers for seamless integration with standard filling processes and equipment.

Our products, outside of our reusable auto-injector and certain systems for targeted drug delivery, are designed to be supplied to customers as sub-assembly components. Such sub-assembly components are ready for filling with a measured dose of an injectable therapy, and the final assembly or packaging is conducted by our

customers. Once our products have been filled, assembled and/or packaged by our customers with an injectable therapy, they become classified for regulatory purposes as drug-device combination products. We expect to submit most of our products to the U.S. Food and Drug Administration, or the FDA, as a Medical Device Master File, or MAF, or Type III Drug Master File, or DMF, for reference by the FDA when our customers are seeking FDA approval for their specific drug-device combination products. In such instances, our customers will ultimately be responsible for seeking and obtaining regulatory approval of the drug-device combination product. Each of our supply agreements that are currently in effect reflect such business-to-business partnerships under which we will sell our products to pharmaceutical customers who are ultimately responsible for the regulatory approval, marketing and sale of the drug-device combination product. Although we may also submit some of these devices to the FDA as a 510(k) filing for clearance or premarket approval, as appropriate for the class of device (or other foreign regulatory processes), our customers would remain responsible for regulatory approval of the drug-device combination product. With respect to our reusable auto-injectors and certain systems for targeted drug delivery – which we could sell directly to a health care provider or end user without having the device pre-filled by a pharmaceutical company – we would submit such products to the FDA as a 510(k) filing for clearance or premarket approval, as appropriate for the class of device (or other foreign regulatory processes), and we would be responsible for the regulatory approval, marketing and sale of the applicable device. At the present time, none of our current product platforms has been evaluated by the FDA.

Our modern U.S. production facility, advanced operational capabilities, experienced management team, quality and regulatory processes, and industry relationships allow us to support the injectable drug delivery requirements of our customers during the clinical development, regulatory approval and lifecycle management of their injectable therapies.

Although we have signed many long-term contracts with large pharmaceutical companies and are meeting our obligations under those contracts, none of our devices has been used by patients for use with a prescribed therapy to date.

Long-Term Customer Collaborations

Our proprietary injectable drug delivery systems can become part of the regulatory label for our customers' drug-device combination products. In some cases, our products may be an important factor in the regulatory approval, clinical use and marketing of our customers' drug-device combination products. In light of the length of regulatory processes, clinical requirements, investment in product development, uniqueness of our proprietary technology and/or other commercial factors that may be involved with switching to an alternative supplier of an injectable drug delivery system, our customers often seek to secure long-term continuity of supply for our products by signing supply contracts with us that can span periods of up to 15 years.

Prior to the supply of a product to our customers, we may receive payments from our customers in connection with upfront or exclusivity fees or the customization of our product platforms to address specific customer, therapy, patient or commercial requirements. Some customers seek to have a customization program completed prior to the signing of a commercial supply contract. Others may sign customization and supply contracts that encompass all stages of a long-term collaboration, including commercial sales.

We believe that our long-term supply contracts will provide predictable, recurring revenue and intrinsic growth that can be generated over periods of up to 15 years or more. We also expect to generate attractive blended operating margins as products from across our various platforms reach peak sales volumes.

Diversified Revenue Sources

There are multiple revenue streams that can be derived from various customer agreements, including product sales, milestone-based customization program payments, upfront fees, exclusivity payments and royalties

from sales. The combination of revenue streams generated from each customer can vary, based upon specific contract terms, timing, the scope of customization requirements, the commercial opportunity for the target therapy, as well as other competitive market factors.

A significant proportion of our revenue to date has been derived from customer payments relating to the customization of products from one or more of our platforms to address specific customer, therapy, patient or commercial requirements prior to the commercial launch of the drug-device combination product. Customers have also paid us upfront or exclusivity fees prior to the commercial launch of their drug-device combination products utilizing one or more of our product platforms. As our customers scale-up to, and begin, commercial launch of such drug-device combination products utilizing our products, we believe that product sales will progressively become a greater proportion of our total revenue.

Use of Our Products by Our Customers

Our products are designed for supply to customers, or their appointed contract manufacturing organizations, in a sterile format where they are ready to be filled, assembled and/or packaged with a measured dose of an injectable therapy. We utilize standard materials within our products to support drug compatibility requirements. Components and related materials such as glass and elastomers are purchased by us from a network of established suppliers. These components and related materials are shipped either to our production facility in York, Pennsylvania, or to the designated facilities of production and supply partners such as Flextronics, where they are manufactured into sub-assembly components. We then supply these sub-assembly components in a sterile format to our customers for integration with their standard filling and packaging processes and equipment.

In addition to being responsible for the filling, assembly and/or packaging of the drug-device combination product, our customers are responsible for the regulatory approval of their drug-device combination product by agencies such as the FDA, the European Medicines Agency, or EMA, or other foreign regulatory authorities, as well as the sale and marketing of their final drug-device combination product.

Ongoing Commitment to Research and Development

We believe that continual investment in research and development is important to the development and sale of our innovative, proprietary products and related services. Our research and development investments are largely aligned to current programs with pharmaceutical and biotechnology companies, as well as our internal capacity to identify and address other unmet or emerging market needs for the delivery of injectable therapies. In this way, our investment in research and development is customer-centric, and intended to support existing customer programs or culminate in the future signing of long-term supply contracts. We believe our large and growing intellectual property portfolio helps protect us against competitors' launching products similar to ours. We also believe that our intellectual property portfolio can help to enhance the competitiveness of the drug-device combination products that may be approved and marketed by our customers.

Product Platforms

We have developed a broad portfolio of innovative, differentiated injectable drug delivery systems that are designed for use with a range of injectable therapies. Existing and prospective customers can select from a series of platform-based technologies across device segments including pre-filled syringes, wearable injectors, insulin delivery systems, disposable and reusable auto-injectors, drug reconstitution delivery systems, ocular delivery systems and other systems for the targeted delivery of injectable therapies. Multiple product configurations and proprietary features are available within each platform, and we are able to further customize each product to specific customer, therapy, patient or commercial requirements.

Average selling prices for our products can vary significantly across various platforms. Pricing within each platform can also vary depending upon the level of product customization required, the number of units to be

purchased by the customer, as well as other market dynamics. In general, our products can range in price from less than \$1 to hundreds of dollars per unit. Customization, industrialization, development and licensing fees accounted for substantially all of our consolidated revenue during the fiscal years ended June 30, 2015, 2014 and 2013. Our product platforms are discussed below.

Pre-filled Syringes

The Unifill® platform is designed to accommodate the majority of injectable therapies suitable for containment in a single-chamber pre-filled syringe for administration via routes including subcutaneous injection, intramuscular injection, or intravenous infusion. To support shelf-life periods of up to two years or more, Unifill® products utilize standard (U.S. Pharmacopeia (USP Class VI) compliant) materials such as glass and elastomers within the drug fluid path. They are supplied in a sterile format to our customers ready for filling, assembly and/or packaging with a measured dose of an injectable therapy utilizing standard filling processes and equipment.

The majority of products within the Unifill® platform include an automatic, user-controlled needle retraction mechanism designed to protect those at risk of needlestick injuries. Once a patient, provider or caregiver injects a customer's therapy into the patient, the needle automatically retracts into the syringe. This integration of an automatic needle retraction within the product can help to eliminate costs and extra steps traditionally associated with the purchase, attachment and activation of bulky add-on (ancillary) safety products onto a standard pre-filled syringe. Independent human factor user studies sponsored either by us, or by pharmaceutical companies evaluating our products, reflect high acceptance and preference rates for our Unifill® and Unifill Finesse® products, which form the basis for our Unifill® platform, by health-care providers and target patient populations. In addition to delivering injectable therapies, certain products within the Unifill platform are also designed with luer connectivity to enable the delivery of therapies via intravenous infusion, thereby increasing the potential use and flexibility of the Unifill® platform.

Product configurations within the Unifill® platform include:

- *Unifill®*- A pre-filled syringe with integrated, automatic and user-controlled retraction.
- *Unifill Finesse®* - Combines integrated, automatic and user-controlled retraction with a standard plunger seal and plunger rod.
- *Unifill Select™* - Allows the end-user to select and attach a needle with a proprietary connection at the time of injection, with automatic, user-controlled needle retraction.
- *Unifill Nexus™* - Equipped with an integrated luer adapter to provide universal connectivity with needleless luer access devices such as intravenous infusion lines or ports.
- *Unifill Allure™* - Allows the end-user to select and attach a needle with a universal luer connection at the time of injection, with automatic, user-controlled needle retraction.

Wearable Injectors

The *ReadyToGo™* portfolio of wearable injectors is designed to support growing demand for pre-filled, disposable devices that can be worn by a patient over periods such as several minutes or several hours during the subcutaneous injection of therapies such as viscous, large-dose volume biologics. The *ReadyToGo™* portfolio of wearable injectors consists of the Precision-Therapy® platform of bolus injection devices and the Flex-Therapy® platform of basal infusion devices. Both of these wearable injector platforms are designed for supply by pharmaceutical and biotechnology companies and are pre-filled, pre-assembled and ready-to inject for simple and convenient self-injection by a patient outside of healthcare facilities, to minimize disruption to normal daily life during the period of therapy administration.

These scalable, flexible platforms utilize standard materials such as glass cartridges and elastomers, do not require sterilization in their final form (terminal sterilization), and are designed ready for integration with our customers' standard filling processes and equipment. Each wearable injector product can be pre-configured to control the duration, rate and volume of dose delivery for an injectable therapy to the target patient. Our wearable injector products require only three simple steps of use: (1) peel off the label, (2) stick the product onto the body and (3) click the button to commence the injection.

Our wearable injectors can be configured to include a soft Flexwear™ catheter that is automatically inserted into the body with the needle, and the catheter remaining in the body following retraction of the needle, enabling drug delivery and supporting patient comfort during drug delivery. Another feature of our wearable injections is a user interface with visual, audible, and/or tactile signals that inform the user during each stage of use. With many pharmaceutical and biotechnology companies seeking to select one wearable injector technology for use with a portfolio of injectable therapies, we have developed our platform so that each product can be efficiently customized to address specific therapy, patient or commercial requirements. Multiple customization options are available, including: dose volume ranges from 1mL up to 30mL; adaptability for drug dose viscosity; pre-configurable delivery duration periods from seconds to hours; bolus, basal, or variable dose delivery rates; and data connectivity via Bluetooth, WiFi, or mobile broadband.

Insulin Delivery

One of our newest innovations is the Imperium™ platform of instant patch pumps for insulin. Designed to be prefilled with insulin and supplied ready for compact, convenient and intuitive multi-day wear, the Imperium™ platform is intended to empower patients to gain control over their blood glucose levels. As a prefilled, high-precision device, this platform is capable of delivering highly concentrated insulins up to U-500. The Imperium™ platform leverages proprietary features and functionality from our Precision-Therapy® and Flex-Therapy® wearable injector platforms, including ease-of-use, utilization of standard materials and integration into established pharmaceutical filling processes and equipment, a range of customization options, and data connectivity. The Imperium™ platform is designed for supply in a sterile format to insulin providers ready for filling and packaging with a measured dose of insulin.

The Imperium™ platform may be configured to have a preset basal rate for continuous subcutaneous insulin infusion, as well as the ability to provide on-demand bolus deliveries through a simple push of the button. Sharing the pre-filled and pre-assembled characteristics of insulin pens, this platform requires no handheld controllers or other ancillary equipment to control or initiate insulin therapy. The Imperium™ platform is compact in size for comfortable, discreet multi-day wear and convenient needle-free disposal. The Imperium™ platform also provides multiple, redundant features to prevent over-delivery of insulin. We believe the Imperium™ platform has the capacity to deliver the therapeutic advantages of an insulin drug pump, but with the simplicity and low cost of an insulin pen.

Auto-Injectors

We have a platform of disposable and reusable auto-injectors that are designed for use with pre-filled syringes from our Unifill platform. We believe our auto-injector platform is broader than our competitors' device lines and contains unique features, including the provision of audible, tactile and visual end-of-dose indicators and needle-free disposal. Our auto-injectors can be customized to address specific customer, therapy, patient and commercial requirements, with product configurations including:

- *LISA™ smart reusable auto-injector* - An automated and highly-customizable product that can be used by a patient to perform hundreds of injections. Patients can control the speed of dose delivery to help minimize pain or discomfort during an injection. It allows for the use and removal of a Unifill syringe with a retracted needle for safe, compact and convenient disposal. Other features include a single

activation button, LED indicators and an on-skin sensor to minimize potential drug wastage. Customization options include data connectivity via Bluetooth, WiFi, RFID / NFC or mobile broadband. Such connectivity can enable operations such as tag reading to verify the use of the correct drug, expiry date and concentration, a touchscreen display, pre-injection drug warming and dose adjustment.

- *RITA® disposable auto-injector* - An ergonomic single-use product with minimal steps of use and no visible springs or mechanisms. An audible, tactile click signals the delivery of the full dose to minimize potential drug waste. For safe, convenient disposal of the used product, the needle is automatically retracted and contained after use.

Drug Reconstitution Delivery Systems

We have a broad portfolio of dual-chamber pre-filled syringes under our EZMix® platform designed for the reconstitution of dry (lyophilized or powder) therapies, or the mixing of liquid-liquid combination therapies. Unlike some competitor products, the process of reconstitution with EZMix® syringes is ventless and orientation-free to minimize the risk of drug loss and reduce the potential for user error. Our products feature standard materials and are designed for integration with pharmaceutical companies' standard filling processes and equipment. A number of fully integrated features are available, including automatic, user-controlled needle retraction, automatic drug reconstitution and the use of staked needles, attachable needles or connectivity with needleless luer access devices. Product configurations available within the platform include:

- *AutoMix Presto™* - Automatic reconstitution for error-free, single-step mixing and injection.
- *EZMix Genesis™* - Orientation-free, ventless one-step reconstitution and automatic, user-controlled retraction.
- *EZMix Engage™* - One step reconstitution with the ability to attach and automatically retract a needle.
- *EZMix Prodigy™* - A compact, single-barrel reconstitution system in a standard pre-fillable syringe format in sizes from 1mL to 50mL.

Ocular Delivery Systems

We have a number of innovative technologies designed for the localized or targeted delivery of ophthalmic therapies to the eye. Ocular delivery systems include:

- *Ocu-ject®* - Accurate, precise delivery of microliter sized doses to the eye, capable of achieving precise delivery of microliter doses from 10uL to 500uL. The Ocu-ject® platform may be readily configured for the desired use model, including: fill-at-time-of-use delivery; prefilled with a luer connection needle; or prefilled with a staked or fixed needle.
- *Ocu-mix®* - A dual-chamber syringe platform to reconstitute or mix, and deliver one or more therapies into the eye with a single injection. The Ocu-mix® platform may be readily configured for the desired use model, including: containing a lyophilized drug in the distal chamber and a diluent in the proximal chamber; containing prefilled drugs or a drug-and-diluent in both chambers; or containing a prefilled drug or a diluent in the proximal chamber and permitting the user to fill the distal chamber at-time-of-use. The dual chamber platform may be further configured to permit delivery of a mixed fluid, or delivery of two separate fluids in sequence. Additionally, the Ocu-mix® platform may be configured to integrate the capabilities of the Ocu-ject® platform to provide accurate, precise delivery of mixed substances.
- *Depot-ject®* - Precise placement of a drug depot into the eye with the clinician having full control over the site of implantation.

Other Drug Delivery Systems

We have a strong background in the development of novel drug delivery systems that can enable and enhance the commercialization and administration of specialized injectable therapies, such as those designed for organ delivery and those that are unsuitable for use with conventional device technologies. For example, our Micro-Ject™ delivery system is designed to optimize the accurate and precise delivery of therapies with microliter doses that are unsuited to conventional device technologies, including to the eye or other organs.

Research and Development

Our ability to compete successfully depends heavily upon our ability to develop innovative, proprietary products and related services. While we believe we have now achieved a critical mass of products for the delivery of most injectable therapies, we continue to invest in research and development to support existing customer programs and to develop new technologies that enhance existing product platforms.

As part of our commitment to identify and address unmet or emerging market needs for the delivery of injectable therapies, we pursue a platform-based approach to product design that encompasses product development capabilities and state-of-the-art manufacturing technology. The base technology underlying each platform is fully developed, and protected by a comprehensive intellectual property portfolio. Our approach to modular product design and scalable manufacturing enables customizations for each product to be integrated into flexible assembly processes.

Our customer-centric business structure enables us to respond quickly and efficiently to customer requirements. We have established cross-functional business teams within each product platform that possess deep scientific expertise and strong technical capabilities. This strong level of industry and product expertise and customer-centric business structure represents a key competitive advantage allowing us to develop and supply innovative, customized products with accelerated timelines.

We incurred research and development expenses of \$52.5 million, \$34.1 million, and \$21.7 million during fiscal years 2015, 2014 and 2013, respectively.

Sales and Marketing

Our existing and prospective customers are pharmaceutical and biotechnology companies that develop and market a range of injectable therapies to treat a large number of acute and chronic diseases. The majority of these existing and prospective customers are large, multinational businesses based in the U.S., Europe, Japan and the Middle East. Our customers typically have a number of injectable therapies, such as biologics, that are either approved or in clinical development and can be combined with our products to create a drug-device combination product. Customers are responsible for the regulatory approval of drug-device combination products, and assuming such approvals are obtained, for the marketing and sale of such drug-device combination product as well. If we sell a device directly to healthcare providers or end users without having a pharmaceutical company prefill the device with a drug, then we will instead be responsible for the regulatory approval of the device and for the marketing and sale of such device, assuming we obtain regulatory approval.

We use a variety of direct channels to secure business with existing and prospective customers. In particular, we believe that our ability to secure long-term customer agreements is enhanced by having a commercial development team with deep industry expertise and a strong network of relationships with pharmaceutical and biotechnology companies. This team is regularly in discussion with existing and prospective customers to identify and address their immediate or emerging requirements.

Much of our new business is generated from existing or prospective customers who want us to customize products from one or more platforms within our portfolio to address specific requirements for their injectable therapies prior to the anticipated commercial launch of their drug-device combination product. We have also

experienced a growth in our business opportunities from existing customers who have expressed desires to: (i) utilize our customizable device platforms for additional drug programs or indications; and/or (ii) leverage additional device platforms from our portfolio to address the market needs of their broader drug pipeline. Accordingly, a number of existing customers are evaluating Unilife's broad range of device offerings for these purposes.

In addition to the work of our commercial development team, we also generate commercial business opportunities by more traditional means such as our website (www.unilife.com), participation at industry conferences, publication of editorial content and advertising within industry media.

Customer Relationships

We are at various stages in the establishment and expansion of commercial relationships with a growing number of pharmaceutical and biotechnology companies. It can typically take on average between one and three years to execute a commercial supply agreement with a customer once a product request or business opportunity has entered our commercial pipeline. During this developmental period, we and our prospective customer may enter into one or more initial agreements that may include transfer agreements or feasibility agreements whereby we may undertake a technical review process covering matters such as product development, quality control, regulatory affairs, marketing, clinical affairs, manufacturing, material selection, formulation science and human factor studies. We may receive revenue from the prospective customer during the product development and evaluation period in connection with services we may perform or evaluation units of our products we supply during the period.

Once we are selected by a customer to customize or supply injectable drug delivery systems for use with one or more of their injectable therapies, we typically begin to generate revenue through sources including milestone-based customization programs, product sales, exclusivity fees, upfront fees or royalties. Certain of our customer contracts include exclusivity rights subject to, for example, annual minimum volume commitments, therapeutic markets and/or product configurations.

As of June 30, 2015, we were generating payments from customer programs across six of our product platforms and involving a variety of our customers' approved brand-name and generic products currently under clinical development. We are not always aware of the products or product candidates for which our customers intend to use our products, and in many instances we are required to keep what information we know about our customers' programs confidential.

Principal Customers

At the present time, although some of our customers have approved therapies, none of our customers has received or applied for regulatory clearance or approval from the FDA or a foreign regulatory authority for the commercial sale of a drug-device combination product that incorporates any of our products. As such, although we commenced initial sales of the Unifill® syringe in the first half of the fiscal year ending June 30, 2015, or fiscal year 2015, and expect to commence sales of some other Unifill product configurations during the first half of the fiscal year ending June 30, 2016, or fiscal year 2016, we do not expect such products will be marketed by customers for commercial use with target drugs during fiscal year 2016. In the meantime, throughout the remainder of fiscal year 2016, we expect that sales of our products may be utilized by our customers for a range of activities including, for example, compatibility studies, filling and packaging line validation, human clinical trials and human factor studies. Some customers may also begin to build inventory of our injectable drug delivery systems for filling with target drugs, in anticipation of scheduled commercial launch. Therefore, our revenue has been historically and is currently predominantly tied to the achievement of milestones and other events that occur from time to time during the various stages in the establishment and expansion of commercial relationships with our customers. As a result, the customers that constitute a larger proportion of our revenue may change from year to year, or quarter to quarter, as different milestones are achieved and other events occur with different customers.

A significant portion of our business is generated by a small number of major customers. As our industry, market demand and our customer base changes, our major customers may also change. Our top three customers generated over 91.0% of our total revenue in fiscal year 2015.

Sanofi for Unifill Finesse®

In September 2013, we signed a long-term supply contract to supply Sanofi with the Unifill Finesse® for use with their anti-thrombotic therapy Lovenox®/Clexane®. The contract period can extend up through calendar year 2024. Following a four year scale-up period after market entry, exclusivity will be maintained, subject to Sanofi purchasing a minimum of 150 million units of the Unifill Finesse or other Unifill syringes per year.

Sanofi for Precision-Therapy®

In September 2014, we signed a worldwide master services and commercial supply agreement with Sanofi to be the sole provider of cartridge-based wearable injectors for all of Sanofi's applicable large dose volume drugs, excluding insulins, for a minimum of 15 years. Additionally, the agreement allows Sanofi to make our wearable injectors available to Sanofi's partners for use with applicable molecules under joint collaborations. In addition to an upfront payment and product sales, we anticipate we will receive approximately \$50 million from customization programs relating to Sanofi molecules and indications. Additional revenue is also expected from customization programs conducted under joint collaborations with Sanofi partners.

MedImmune

In November 2013, we signed an agreement with MedImmune, the global biologics arm of AstraZeneca, to customize and supply products from our platform of wearable injectors for use with several target product candidates from MedImmune's portfolio. We are receiving regular payments for customization services from MedImmune under the agreement.

AbbVie

In January 2015, we entered into a definitive global strategic agreement with AbbVie for the customization and supply of our injectable drug delivery systems for use with AbbVie's drug portfolio. We have been selected by AbbVie as a preferred partner for the customization and supply of innovative, differentiated drug delivery systems. AbbVie paid \$5 million for the exclusive right to form and enter into a mutually-agreeable development and supply agreement with us to include exclusive access to the Unifill Finesse™ prefilled syringe and the LISA™ reusable auto-injector for target therapies within AbbVie's drug portfolio for the treatment of autoimmune diseases, as well as associated exclusivity fees. The target therapies and conditions for which these systems will be used are confidential under the terms of the agreement.

Novartis

In November 2013, we signed an agreement with Novartis to supply clinical products from one of our injectable drug delivery system platforms for use with one of Novartis' early stage product candidates. We began to generate revenue under the Novartis program during the second quarter of fiscal year 2014. Additional payments are expected as the program continues.

Hikma

In November 2013, we signed a long-term commercial supply contract with Hikma for the use of the Unifill syringe, the Unifill Nexus and the Unifill Allure with an initial list of 20 of its generic injectable therapies. Product sales to Hikma commenced during fiscal year 2015. Under the terms of the contract, we expect to supply

Hikma with a minimum volume of 175 million units per year following a high-volume scale-up period. In addition to product sales, we may receive up to \$40 million in upfront and milestone payments from Hikma.

Ocu-ject® ocular delivery agreement

In December 2013, we announced the signing of an agreement with a global pharmaceutical company seeking to use the Ocu-ject™ ocular drug delivery system to deliver a target injectable therapy into the eye. The identity of the global pharmaceutical company, one of the market leaders in ophthalmic therapies, as well as the terms of the agreement were not disclosed for commercial purposes and confidentiality requirements. We began to generate modest revenue under the program in January 2014.

Depot-ject® ocular injection agreement

In December 2014, we announced the signing of a worldwide 10 year commercial supply agreement with a global pharmaceutical company for the use of the Depot-ject® delivery system with an approved ocular injection therapy. We anticipate the commercial availability of Depot-ject® with the target therapy, which is approved in the U.S and Europe for the treatment of a high prevalence disease of the retina, to commence after a 12 to 24 month process of customization and regulatory approval for the drug-device combination.

Additional Customer Discussions

We are involved in a number of additional ongoing discussions with multiple existing and prospective pharmaceutical and biotechnology companies regarding the development, customization and commercial use of products from across our portfolio that may also result in the future signing of additional contracts.

Manufacturing

We assemble our proprietary products at our manufacturing facility in York, Pennsylvania, which is registered with the FDA for the manufacture of medical devices. As discussed below under the header “Component Supply,” we outsource the production of components and other raw materials used in the assembly of our products to third-party suppliers. We supply our products to our customers ready to be filled, assembled and/or packaged with their injectable therapy utilizing standard filling processes and equipment. The filling, assembly and/or packaging of our customers’ drug-device combination products incorporating our products is conducted either by our customers, or a contract manufacturing organization engaged by our customers.

Our manufacturing operations consist of a 165,000 square foot facility located on a 38 acre site in York, Pennsylvania that was opened in December 2010. In addition to multiple Class 7 and Class 8 clean rooms, the facility includes administrative offices, research and development laboratories, prototyping and automation facilities, a warehouse and expansion space. Activities we may undertake at our York facility include product design and development, production of sub-assembly components, packaging, quality assurance and supply chain management. All manufacturing and manufacturing related activities we undertake are guided by advanced business systems, such as SAP ERP that complement those systems commonly used by our customers.

Our quality management system, or QMS, is regularly audited by regulatory authorities for compliance with the requirements of, and certified to, ISO 13485, Medical Devices – Quality Management Systems – Requirements, for regulatory purposes, which is equivalent to Quality System Regulations, or QSR, for FDA compliance. As an FDA registered medical device manufacturer, we are periodically audited by the FDA pursuant to the QSRs and Current Good Manufacturing Practice regulations, or cGMP, with the last audit occurring in 2013 where there were no formal findings. In addition, our QMS is regularly audited by existing and prospective customers.

Existing clean room space is used for the manufacture of components and related materials into sub-assembly components by us using assembly lines. We are in the process of doubling the size of our cleanroom space, and also expanding our building footprint to accommodate additional production infrastructure. We expect to complete the first phase of expansion by November 2015.

The manufacturing systems we use vary depending on the type of product, its stage of commercialization and the unit volume requirements of our customers. We utilize a modular platform-based design for our products to allow for an efficient, scalable approach to manufacturing. We believe that the long-term, forward-looking nature of the supply with our customers, gives us sufficient time to scale-up production capacities in line with demand.

Production capacities vary depending upon the unit volume requirements of our customers and the stage of a product commercialization program. We have assembly lines in place with varying annual production capabilities with additional assembly lines in various stages of installation or procurement to support production scale-up in line with scheduled customer requirements. We expect additional assembly lines for various products or platforms will continue to be installed to support customer demand.

Additionally, in November 2014 we announced the signing of a global strategic alliance agreement with Flextronics, a leading end-to-end supply chain solutions company, to further expand the production capacity and scale-up capability of our product portfolio. Our agreement with Flextronics will support commercial demand from pharmaceutical customers seeking to leverage our products and services to enhance and differentiate their injectable therapies. In addition to using our own FDA-registered manufacturing facilities in York, Pennsylvania, we expect that Flextronics will serve as a secondary source of supply to us and our pharmaceutical customers. Flextronics is a leading and trusted provider of supply chain solutions for the pharmaceutical industry, and has long-term relationships with many of our current and prospective customers. Flextronics and their global manufacturing capabilities further enhance our supply chain network and generate attractive manufacturing and supply chain efficiencies and robustness. Additionally, this partnership may allow for the most efficient capital investment strategy to support our customer demand.

Component Supply

We source components and other materials utilized in the production of our products from a variety of pre-qualified suppliers, with significant expertise in the medical device and pharmaceutical and biotechnology sectors. Some proprietary components are manufactured by appointed vendors utilizing molding equipment that we own. While some of our suppliers are regulated by applicable regulatory bodies, all of our major suppliers are regularly audited by us to ensure compliance with applicable regulatory and quality requirements.

Intellectual Property

Patents, trademarks and other proprietary rights are very important to our business. We generate our own intellectual property and hold numerous patents and patent applications covering our existing and future products and technologies. We also rely on a combination of trade secrets and manufacturing know-how to protect our intellectual property. We enter into non-disclosure agreements with certain vendors and suppliers to attempt to ensure the confidentiality of our technology. We also enter into non-disclosure agreements with our customers. In addition, we require that all our employees sign confidentiality, non-compete and intellectual property assignment agreements. Our focus is to safeguard the intellectual property surrounding our products, manufacturing processes, and other related technologies to protect not only our position and growth opportunities, but also that of our strategic partners and customers.

Our patent portfolio covers current and anticipated product offerings, as well as process improvements and other value-added innovations which streamline our customers' filling processes. Additionally, since our product architecture is focused, at least in part, on component modularity, as new products are configured to meet

customer needs, the modular components of such products are generally covered by existing patents or pending applications and new applications are pursued to cover the specific aggregation or configuration of the modular components. This means that each of our products is protected by virtue of one or more patents or pending applications relating to the product's constituent components. As new products are innovated to meet specific customer, therapy, patient or commercial requirements, such new products will have preliminary patent protection at least to the extent that they leverage one or more of the existing protected components. Similarly, since our product platforms offer broad customizability for our customers, such customized products will be preliminarily protected by our existing patent portfolio which will be strengthened by further patent applications directed to the specific product configurations. We believe that this approach provides broad and readily-available patent protection to Unilife, even at the earliest phase of product development or customization.

As of July 2015, we had approximately 180 issued patents relating to our product platforms across more than 24 worldwide jurisdictions, including the U.S., the European Union, Australia, Japan, Israel, and China. These broad jurisdictions are strategically selected to reflect our customers' markets, competitor spaces, and growth regions. Though granted patents expire at varying dates based on the filing date of the related application, the life of patents relating to our product platforms extends through calendar year 2034. Pending and/or future filed patent applications covering relevant advancements in these technologies could extend well beyond that time period once granted.

We also have over 200 additional patent applications at various stages of examination with the United States Patent and Trademark Office and other international patent organizations, which may be granted as patents over the next two to five years. A significant number of additional patent applications are expected to be filed with national and international patent organizations during fiscal year 2016. The rate of growth in our patent portfolio is reflective of the growth in our product categories and devices, and improvements, methodologies and/or embodiments to meet the specific unmet needs of our growing customer base. Our patent filings broadly cover all of our existing product platforms, and pending applications address product improvements and next generation technologies.

Additionally, we have a broad and growing trademark portfolio. We have secured trademark registrations for the marks UNILIFE®, UNIFILL®, UNITRACT®, UNIFILL FINESSE®, RITA®, PRECISION-THERAPY®, FLEX-THERAPY®, EZMIX®, OCU-JECT®, DEPOT-JECT®, MICRO-JECT®, and OCU-MIX® in the U.S. and, for some such marks, in other key countries. We have pending trademark applications for several of these marks in other jurisdictions. UNIFILL ALLURE™, UNIFILL NEXUS™, UNIFILL SELECT™, EZMIX GENESIS™, EZMIX PRODIGY™, EZMIX ENGAGE™, IMPERIUM™, LISA™, AUTOMIX PRESTO™, READYTOGO™, and FLEXWEAR™ are our common law trademarks in the United States and in many international jurisdictions. We also have trademark registrations and pending applications for our other proprietary product platforms in a number of key countries, including the U.S.

Competition

The market for injectable drug delivery systems is highly competitive. As compared to products such as disposable (hypodermic) syringes, the production and supply of our injectable drug delivery systems is more specialized, with a need for us to conform to high quality expectations and specific requirements. Significant capital investment is required to establish the operational capabilities, quality and regulatory systems and industry expertise to develop, manufacture and supply injectable drug delivery systems such as our product platforms, which can limit the number of new entrants into our market.

We compete against many companies, both public and private, that range in size from small, highly focused businesses to large diversified multinational manufacturers of medical devices and healthcare equipment. Most of these competitors are based in the U.S. and Europe. Some of the large and established companies include Becton, Dickinson and Company, or BD, SCHOTT forma vitrum AG, Gerresheimer Bünde GmbH, West Pharmaceutical Services, Inc., Medtronic MiniMed, Inc., Insulet Corporation, and Ypsomed Group. Collectively, these

companies represent the majority of revenue for our market, with BD and Medtronic MiniMed, Inc. having the largest share. Some of these competitors are also current or potential suppliers of components or materials to us for use with our products.

A core business focus for many of our competitors is the production of commodity components such as glass barrels or elastomers. Unlike our products, these commodity components alone may limit the ability of a pharmaceutical or biotechnology company to utilize a delivery system to differentiate their injectable therapies. Also unlike Unilife, there are few established competitors that take responsibility for the entire injectable drug delivery system, or the integration of a prefilled syringe with an auto injector. Consequently, many pharmaceutical and biotechnology companies commonly purchase glass-based components from one supplier, and elastomer components from another supplier.

The overall market for injectable drug delivery systems is largely fragmented. Aside from BD, there are few competitors that participate in the majority of market segments where we are active. Many competitors participate in only a handful of market segments such as auto-injectors or wearable injectors. In addition to other device companies, we are also subject to potential competition from some customers. In particular, our customers may develop internally or acquire their own injectable drug delivery systems. Moreover, we may face indirect competition from companies who develop and market alternative treatments and delivery methods that compete with our customers' drug-device combination products that utilize our products.

Regulations

Our products, outside of our reusable auto-injector and certain systems for targeted drug delivery, are designed to be supplied to customers as sub-assembly components. Such sub-assembly components are ready for filling with a measured dose of an injectable therapy, and the final assembly and/or packaging is conducted by our customers. Once our products have been filled, assembled and/or packaged by our customers with an injectable therapy, they become classified for regulatory purposes as a drug-device combination product. We expect to submit most of our products to the U.S. Food and Drug Administration, or the FDA, as a Medical Device Master File, or MAF, or Type III Drug Master File, or DMF, for reference by the FDA when our customers are seeking FDA approval for their specific drug-device combination products. In such instances, our customers will ultimately be responsible for seeking and obtaining regulatory approval of the drug-device combination product. Each of our supply agreements that is currently in effect reflects such business-to-business partnerships whereby we will sell our products to pharmaceutical customers who are ultimately responsible for the regulatory approval, marketing and sale of the drug-device combination product. Although we may also submit some of these devices to the FDA as a 510(k) filing for clearance or premarket approval, as appropriate for the class of device (or other foreign regulatory processes), our customers would remain responsible for regulatory approval of the drug-device combination product. With respect to our reusable auto-injectors and certain systems for targeted drug delivery – which we could sell directly to a health care provider or end user without having the device pre-filled by a pharmaceutical company – we would submit such products to the FDA as a 510(k) filing for clearance or premarket approval, as appropriate for the class of device (or other foreign regulatory processes), and we would be responsible for the regulatory approval, marketing and sale of the applicable device.

In order to be eligible to market and sell a drug-device combination product, a customer will need to submit and receive approval of a New Drug Application, or NDA, biologics license application, or BLA, abbreviated new drug application, or ANDA, the appropriate prior approval supplement to an existing NDA, BLA or ANDA, or the foreign equivalent of any of the foregoing, which may include documentation of summative human factor studies, records of completion of all required clinical trials, and compliance with cGMP across the development, production and delivery of the drug-device combination product, including process validation of the commercial-scale manufacturing and assembly processes that will be used to create the components for filling, assembly and/or packaging of the drug-device combination product. For a drug-device combination product, it is possible that our customers will be required to submit marketing applications through both the drug or biologic and medical

device pathways. The process of obtaining FDA marketing clearance or approval is lengthy, expensive, and uncertain. We cannot be sure how the FDA, EMA or other foreign regulatory authority will regulate our customers' drug-device combination products, in which case the path to regulatory approval would be different and could be more lengthy and costly. As an FDA-registered medical device manufacturer and a component supplier to our customers, we are required to comply with cGMP for any products we supply to our customers for clinical or commercial use.

We accordingly maintain our facility certifications and operate our QMS in compliance with FDA, European and other relevant international standards. Doing so minimizes regulatory risk to our customers by demonstrating that we have the ability to supply cGMP-compliant components for their drug-device combination products. For instance, our customers must be able to demonstrate to the FDA or a foreign regulatory authority that the manufacturing and assembly processes for their drug-device combination products are manufactured under cGMP before those processes can be used for clinical or commercial production for the U.S. market. At the appropriate time under each agreement with our customers, we will accordingly provide documentation, establishing that each specific manufacturing and/or assembly process we intend to use for commercial production of components was validated, where appropriate, and manufactured in a manner that conforms with cGMP.

Commercial and Regulatory Status

Our products include our pre-filled syringes, wearable injectors, insulin delivery systems, disposable and reusable auto-injectors, drug reconstitution delivery systems, ocular delivery systems and other systems for the targeted delivery of injectable therapies. It is the responsibility of our customers to apply for and obtain final regulatory approval from the FDA or foreign regulatory authorities of each drug-device combination product that incorporates any of our products before the drug-device combination product can be sold commercially to end users. This is the commercial and regulatory process contemplated in each of our current customer supply agreements.

At the present time, although some of our customers have approved therapies, none of our customers has received regulatory clearance or approval from the FDA or a foreign regulatory authority for the commercial sale of a drug-device combination product that incorporates any of our products. It is also our understanding that none of our customers has applied for regulatory approval of such a drug-device combination product. Therefore, at the present time, none of our products has been sold by our customers with their injectable therapies. Once any of our customers apply for regulatory approval to sell a drug-device combination product, it will be the responsibility of the customer to obtain final product approvals from the FDA or a foreign regulatory authority.

We anticipate that, under the terms of certain customer agreements, we will assist our customers in the preparation and submission of their regulatory approval application. We have previously validated manufacturing and assembly processes in accordance with cGMP for certain customers under contractual agreements. At the appropriate time under each contract, we will provide the necessary documentation to support our customers' application for regulatory approval, including, if applicable, documentation pertaining to process validation.

With respect to our reusable auto-injectors and certain systems for targeted drug delivery – which we could sell directly to a health care provider or end user without having the device pre-filled with a drug by a pharmaceutical company – we would be responsible for the regulatory approval, marketing and sale of the applicable device. At the present time, none of our current product platforms has been evaluated by the FDA.

Other Regulations

Pervasive and continuing regulation

Our customers are subject to pervasive and continuing government regulation by the FDA and various other federal and state agencies and are also subject to similar regulation by foreign governmental agencies. To varying

degrees, such regulatory agencies require compliance by our customers with laws and regulations governing the development, testing, manufacturing, labeling, advertising, marketing, distribution, and post-market surveillance of our customers' drug-device combination products that utilize our products.

510(k) clearance pathway

We expect to submit our products to the FDA as an MAF or DMF when our customers are seeking FDA approval for their specific drug-device combination products or as a 510(k) filing for clearance or premarket approval, as appropriate for the class of device (or other foreign regulatory processes). We expect the majority of our products will be submitted as an MAF or DMF that will be referenced during the review of a submission by a customer for the drug-device combination product. 510(k) submissions may be considered for other products, such as reusable auto-injectors, where we deem appropriate.

If one of our products is classified and regulated as a medical device, we will seek 510(k) clearance or premarket approval, as appropriate for the class of device, from the FDA as well as corollary approvals by foreign equivalents to the FDA. We would then be required to submit certain information to the FDA or other foreign regulatory authority from which we are seeking clearance or premarket approval, and may be required to conduct pre-clinical studies and clinical trials on our products.

Manufacturing and operations

As an FDA-registered medical device manufacturer and a component supplier to our customers, we are required to comply with cGMP for any products we supply to our customers for clinical or commercial use. Our QMS is regularly audited by regulatory bodies, such as the FDA. In addition, our QMS is also regularly audited by existing and prospective customers. Our QMS is fully certified to ISO 13485 and operates in compliance with cGMP for the benefit of our customers. If we are unable to manufacture our products in the quantities and at the prices set forth in our customer agreements, satisfy our customers' manufacturing scale-up needs, comply with cGMP or otherwise meet the specific terms of our customer agreements, such failures could have a material adverse impact on our business, prospects, results of operations, cash flows and financial condition.

We are also subject to various federal, state and local laws and regulations, both in the U.S. and other international territories where we conduct business, relating to such matters as safe working conditions, laboratory and manufacturing practices and the use, handling and disposal of hazardous or potentially hazardous substances used in connection with our research and development and manufacturing operations. Although we believe we are in compliance with these laws and regulations in all material respects, we cannot provide assurance that we will not be required to incur significant costs to comply with such laws or regulations in the future.

Employees

As of June 30, 2015, we had 278 employees, of whom 230 were engaged in operations, including research and development, quality assurance and manufacturing activities, 9 were engaged in sales and marketing activities and 39 were engaged in finance, legal and other administrative functions. Most of our employees are located at either our York, Pennsylvania facility or the Unilife Innovation Center in King of Prussia, Pennsylvania. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relations with our employees to be good.

Corporate History

Unilife was incorporated in Delaware on July 2, 2009 as a wholly-owned subsidiary of UMSL. On January 27, 2010, Unilife became the parent company of UMSL upon completion of the redomiciliation under Australian law and UMSL's stockholders and option holders exchanged their interests in UMSL for equivalent

interests in Unilife. On February 16, 2010, Unilife's common stock began trading on The NASDAQ Stock Market LLC under the symbol "UNIS." Our principal executive offices are located at 250 Cross Farm Lane, York, Pennsylvania 17406. Our telephone number is (717) 384 3400.

Financial Information about Geographical Areas

See Note 3 to our consolidated financial statements for information regarding our revenue by geographic area.

Available Information

We maintain an internet website at www.unilife.com. Our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports are available free of charge through the "Investor Relations" portion of our website, as soon as reasonably practicable after they are filed with the Securities and Exchange Commission. The information posted on our website is not incorporated into this Annual Report on Form 10-K.

Item 1A. Risk Factors

Our business faces many risks. We believe the risks described below are the material risks that we face. However, the risks described below may not be the only risks we face. Additional unknown risks or risks that we currently consider immaterial may also impair our business operations. If any of the events or circumstances described below actually occurs, our business, financial condition or results of operations could suffer, and the trading price of our shares of common stock could decline significantly. Investors should consider the specific risk factors discussed below, and the other information contained or incorporated by reference herein and the other documents that we file from time to time with the Securities and Exchange Commission.

Risks Relating to Our Business

We need additional funding to continue our operations and meet our research and development, capital and general and administrative expenses. Such funding may not be available on favorable terms, if at all, and may be dilutive to our existing stockholders. Without modifications to our existing payment obligations or receipt of additional funding, our existing cash and other sources of liquidity may not be sufficient to fund our operations through September 2016. If additional capital is not available, we may have to further curtail our operations, or take other actions that could adversely impact our shareholders.

Our business does not generate the cash necessary to finance our operations and has consumed substantial amounts of cash to date. We incurred net losses during fiscal years 2015, 2014 and 2013 of \$90.8 million, \$57.9 million and \$63.2 million, respectively. We expect to continue to incur losses and use cash during fiscal year 2016 and through at least fiscal year 2017. Without modifications to our existing payment obligations or receipt of additional funding, we will require additional capital to continue our operations beyond September 2016. At June 30, 2015, we had cash and cash equivalents totaling \$12.3 million, excluding restricted cash.

Our near-term capital needs depend on many factors, including:

- our ability to carefully manage our costs;
- the amount and timing of revenue received from customer contracts;
- our ability to successfully utilize currently existing equity facilities;
- our success in promptly establishing a strategic alternative that is in our shareholders' best interests.

Under a cost reduction and business realignment initiative implemented as of the date of this report, we have reduced our headcount by approximately 50 employees, or approximately 17% of our workforce, and we will significantly reduce operating expenses in fiscal 2016.

On September 2, 2015, we announced that in response to third-party initiated expressions of interest, we retained Morgan Stanley & Co. LLC, an investment banking firm, to assist us in reviewing and evaluating a full range of strategic alternatives to enhance shareholder value. The strategic alternatives could include a possible sale of the Company, a strategic partnership with one or more parties or the licensing of some of our proprietary technologies, or other possible transactions. There is no assurance, however, that we will be able to raise sufficient capital or engage in any strategic transaction on acceptable terms, if at all.

If we raise additional funds through the issuance of equity securities, the percentage ownership of our existing stockholders will be reduced, our stockholders may experience additional dilution in net book value, and such equity securities may have rights, preferences or privileges senior to those of our existing stockholders. On July 29, 2015, we entered into an equity purchase agreement, or the Purchase Agreement, with Lincoln Park Capital Fund, LLC, or LPC, a Chicago-based institutional investor, whereby we have the right to sell up to \$45 million in shares of our common stock through July 2017, subject to certain limitations and conditions set forth in the Purchase Agreement. Pursuant to the Purchase Agreement, LPC initially purchased \$5 million in

shares of our common stock. As consideration for entering into the Purchase Agreement, we issued to LPC 451,354 shares of our common stock. We did not receive any cash proceeds from the issuance of these shares. On the same day, we also entered into a Controlled Equity OfferingSM Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., or Cantor, whereby we implemented a \$25 million At-the-Market facility that can be used from time to time, subject to the limitations set out in the Sales Agreement. We intend to balance the use of these facilities with our customer cash receipts and any additional funds we may receive from customer access or exclusivity fees for our products.

If we are unable to obtain adequate financing or engage in a strategic transaction on acceptable terms when needed, we will be required to implement further cost reduction strategies. These reductions could significantly impact activities related to the commercialization and sale of our products, and could result in significant harm to our business, financial condition and results of operations. In addition, these reductions could cause us to further curtail our operations, or take other actions that would adversely impact our shareholders. If we are unable to secure additional financing on terms acceptable to us and on a timely basis, we may seek stockholder approval to downsize or wind down our operations through liquidation, bankruptcy or a sale of our assets.

The impact and results of our exploration of strategic alternatives are uncertain and may not be successful.

On September 2, 2015, we announced that in response to third-party initiated expressions of interest, we began a process to explore and consider a full range of strategic alternatives available to us to enhance shareholder value. Strategic alternatives could include a possible sale of the Company, a strategic partnership with one or more parties or the licensing of some of our proprietary technologies, or other possible transactions. We engaged Morgan Stanley & Co. LLC as our financial advisor to assist us in this process. There can be no assurance that this exploration process will result in any initiatives, agreements or transactions that will enhance shareholder value. Further, any strategic transaction that is completed ultimately may not deliver the anticipated benefits or enhance shareholder value.

In addition, there is uncertainty regarding the length and/or complexity of the strategic-alternative exploration process. We also expect that the process will continue to distract the attention of our management from operating and growing our business and may impair our relationships with our customers, partners and employees. It is also possible that we will incur significant expenses pursuing one or more transactions unsuccessfully. We do not currently intend to disclose further developments with respect to this process, unless and until our board approves a specific transaction or otherwise concludes its review of strategic alternatives.

We need additional funding to meet our capital needs and our debt obligations include covenants which may limit our ability to raise capital.

The Amended OrbiMed Credit Agreement and the Metro Bank Loan (each defined below) contain certain restrictive covenants. The Amended OrbiMed Credit Agreement contains certain customary covenants, including among other things, covenants relating to financial performance and liquidity targets. The Amended OrbiMed Credit Agreement contains covenants that, among other things, require us to obtain consent from the Lender prior to incurring certain indebtedness or assuming or guaranteeing the indebtedness of another entity or individual. Moreover, the Metro Bank Loan is secured by a mortgage lien and a continuing security interest in Cross Farm's personal property, and contains certain customary covenants, including the maintenance of \$2.4 million of restricted cash that must remain in cash deposits (on which Metro Bank has a first priority security interest). In addition, we are required to maintain a cash balance of \$5.0 million inclusive of the \$2.4 million of restricted cash. Furthermore, the issuance of equity securities in excess of 40% of our outstanding shares of common stock to a person or group (within the meaning of Rule 13d-5 of the Exchange Act) constitutes an event of default under the Amended OrbiMed Credit Agreement. If we raise additional funds from debt or equity financing, these restrictive covenants may limit our ability to raise capital, if at all. If we are unable comply with such covenants or obtain a waiver from our lenders, then it may be more difficult for us to operate our business or we may default on our obligations to our lenders.

Our fiscal year 2015 consolidated financial statements state that our recurring losses from operations and limited cash resources raise substantial doubt about our ability to continue as a going concern.

Our continuation as a going concern is dependent upon our attaining and maintaining profitable operations, generating continued cash payments from customers under new or existing contracts and/or raising additional capital. In addition, our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Our liquidity is highly dependent on our available financing facilities and our ability to improve our financial condition. Our failure to obtain new or additional financing could impair our ability to both serve our existing customer base and develop prospective customers and could result in our failure to continue to operate as a going concern.

The uncertainty regarding our ability to continue as a going concern may have an adverse effect on our customer and supplier relationships.

Our relationships with our existing and prospective customers and suppliers are predicated on the belief that we will continue to operate as a going concern. Certain of our existing customers may terminate their agreements with us and certain of our prospective customers may not enter into agreements with us if there is uncertainty regarding our ability to continue as a going concern. This may have an adverse effect on our ability to grow our revenue, which is a key component of our plan to continue as a going concern. Current and future suppliers may be less likely to grant us credit, resulting in a negative impact on our working capital and cash flows.

We do not expect to be profitable until we either achieve commercial scale production and sales of our proprietary injectable drug delivery systems or receive sufficient upfront fees and other payments from customers to offset our total operating expenditures.

At the present time, while some of our customers have approved therapies, none of our customers has received regulatory clearance or approval from the FDA or a foreign regulatory authority for the commercial sale of a drug-device combination product that incorporates any of our products. It is also our understanding that, at the present time, none of our customers has applied for regulatory approval of such a drug-device combination product. None of our products is currently being sold by our customers with their injectable therapies. To date, we have derived substantially all of our revenue from upfront payments, exclusivity fees and milestone-based fees from customers. Many of our customers' injectable therapies that are planned to be used in combination with our products are in various stages of clinical development.

We have a broad portfolio of proprietary product platforms, including pre-filled syringes, wearable injectors, insulin delivery systems, disposable and reusable auto-injectors, drug reconstitution delivery systems, ocular delivery systems and other systems for the targeted delivery of injectable therapies. We have incurred, and will continue to incur, significant research and development expenses related to the development and manufacturing scale-up of our proprietary portfolio of injectable drug delivery systems. We have also continued to invest in our facilities and in capital equipment in the amount of \$16.6 million during fiscal year 2015. We are also installing additional clean room manufacturing space within the existing footprint of our York facility that will accommodate additional assembly lines and related activities. In addition, during fiscal year 2015, we increased headcount by 69 employees (consisting mostly of employees focused on research and development) and invested \$52.5 million to address our research and development requirements, including employee costs, equipment, materials, tooling, prototypes and outside contract services. We expect to continue investing in capital equipment to support increasing customer demand for our products and services. We will also incur significant general and administrative expenses such as assisting our customers with seeking regulatory approvals and complying with the requirements related to being a public company in both the United

States and Australia. We do not expect to be profitable until we generate sufficient revenue from product sales, upfront fees, milestone-based payments or royalty fees to offset our total operating expenditures. Even then, our research and development, capital and general and administrative expenses will need to be at a reasonable cost and volume level for us to be profitable.

If we experience problems or delays in securing additional agreements to supply our products and services to customers, our business, including our ability to generate additional revenue, will be materially and adversely affected.

To date, we have signed commercial supply contracts and other agreements with several pharmaceutical and biotechnology companies. However, our ability to generate additional revenue will also depend on our ability to successfully negotiate additional agreements for our proprietary product platforms with new or existing customers and, notwithstanding potential upfront or milestone-based payments, to begin supplying substantial commercial quantities of such products under such agreements. Given the substantial size, complexity and long-term duration of many of these prospective agreements, they can take significant time to negotiate and finalize. While we are in advanced stages of negotiating some of these agreements, we cannot provide assurance of if or when we will be able to enter into any additional agreements for our products or what the terms of any such agreements will be. If we are unable to secure additional supply agreements for our products and services in a timely manner or obtain favorable terms under such agreements, our ability to generate additional revenue aside from our existing contracts will be materially and adversely affected.

Our devices will be subject to regulatory oversight and approvals either as combination products or as devices. We cannot be sure how the FDA, EMA or other foreign regulatory authority will regulate our customers' drug-device combination products or our devices and/or whether we or our customers will be successful in obtaining and/or maintaining regulatory approval.

Our products, outside of our reusable auto-injector and certain systems for targeted drug delivery, are designed to be supplied to customers as sub-assembly components. Such sub-assembly components are ready for filling with a measured dose of an injectable therapy, and the final assembly or packaging is conducted by our customers. Once our products have been filled, assembled and/or packaged by our customers with an injectable therapy, they become classified for regulatory purposes as drug-device combination products. We expect to submit most of our products to the U.S. Food and Drug Administration, or the FDA, as a Medical Device Master File, or MAF, or Type III Drug Master File, or DMF, for reference by the FDA when our customers are seeking FDA approval for their specific drug-device combination products. In such instances, our customers will ultimately be responsible for seeking and obtaining regulatory approval of the drug-device combination product. Each of our supply agreements that are currently in effect reflect such business-to-business partnerships under which we will sell our products to pharmaceutical customers who are ultimately responsible for the regulatory approval, marketing and sale of the drug-device combination product. Although we may also submit some of these devices to the FDA as a 510(k) filing for clearance or premarket approval, as appropriate for the class of device (or other foreign regulatory processes), our customers would remain responsible for regulatory approval of the drug-device combination product. With respect to our reusable auto-injectors and certain systems for targeted drug delivery – which we could sell directly to a health care provider or end user without having the device pre-filled by a pharmaceutical company – we would submit such products to the FDA as a 510(k) filing for clearance or premarket approval, as appropriate for the class of device (or other foreign regulatory processes), and we would be responsible for the regulatory approval, marketing and sale of the applicable device.

In order to be eligible to market and sell a drug-device combination, a customer will need to submit and receive approval of an NDA, BLA, ANDA or the foreign equivalent of any of the foregoing, which shall include documentation of summative human factor studies and records of completion of all required clinical trials.

For a drug-device combination product, it is possible that our customers will be required to submit marketing applications through both the drug or biologic and medical device pathways. The process of obtaining FDA marketing clearance or approval is lengthy, expensive, and uncertain. We cannot be sure how the FDA,

EMA or other foreign regulatory authority will regulate our customers' drug-device combination products, in which case the path to regulatory approval would be different and could be more lengthy and costly. We also cannot be sure that our customers' drug-device combination products will be cleared or approved in a timely fashion, or at all, which could impact our customers' ability to market their drug-device combination products that utilize our products. If the FDA does not approve or clear the drug-device combination products in a timely fashion or at all, or if there are ongoing issues with obtaining approval of drug-device combination products involving our proprietary product platforms and our customers' injectable therapies, our business and financial condition will be adversely affected.

Moreover, the approval process may also require changes to our customers' drug-device combination products or result in limitations on the indicated uses of our customers' drug-device combination products, which could negatively effect us. As a result, our customers' expectations with respect to marketing approval or clearance may prove to be inaccurate, and our customers may not be able to obtain marketing approval or clearance in a timely manner or at all. We could face similar issues if we submit any devices to the FDA as a 510(k) filing for clearance or premarket approval, as appropriate for the class of device (or other foreign regulatory processes). We may be required to make changes to our device or we may not be able to obtain marketing approval or clearance in a timely manner or at all.

In addition, regulatory requirements in the United States and outside the United States can, at any time, require prompt action to maintain compliance, particularly, when product modifications are required. Following the introduction of a drug-device combination product or a device, these agencies will also periodically review our manufacturing processes and the performance of our customers' drug-device combination products or our devices.

Our failure to comply with cGMP, and our customers' or our failure to comply with adverse event reporting, clinical trials and other requirements of these agencies could delay or prevent the production, marketing or sale of our customers' drug-device combination products or our devices and result in fines, delays, suspensions or prevention of regulatory clearances, closure of manufacturing sites, seizures or recalls of products and damage to our and our customers' reputation.

We and our customers are subject to extensive regulation by governments around the world, and if these regulations are not complied with, existing and future operations may be curtailed, and we could be subject to liability.

Our devices and our customers' drug-device combination products that utilize our products are subject to extensive regulation by governmental authorities in the United States, Europe and other countries, including the FDA. Not only do these regulations present challenges during the regulatory approval process as discussed above, but after our devices or our customers' drug-device combination products that utilize our products are approved and placed in the market, numerous regulatory requirements apply. These include, but are not limited to QSR, labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or "off label" uses, medical device reporting regulations and post-market surveillance regulations, and laws and regulations that govern the development, testing, manufacturing, advertising, marketing and distribution of medical devices, including our devices and our customers' drug-device combination products that utilize our products. The FDA has broad post-market and regulatory enforcement powers.

As a registered device manufacturer and supplier of the drug delivery device component of a combination product, we are subject to unannounced and preapproval inspections by the FDA of our manufacturing facility to determine our compliance with QSR and cGMP.

Failure to comply with applicable regulatory requirements can result in an enforcement action by the FDA, which may include any or all of the following sanctions: fines, injunctions, consent decrees and civil penalties, recall or seizure of our products or our customers' drug-device combination products, operating restrictions, partial suspensions or total shutdown of production, refusing our customers' requests for regulatory approvals of

their drug-device combination products or new intended uses, as applicable, refusing our requests for regulatory approval of our devices, withdrawing our customers' or our regulatory approvals that may be granted and criminal prosecution.

The therapeutic efficacy of many of our customers' therapies is either unproven in humans or has only been proven in limited circumstances, and we may not be able to successfully develop and sell our products in combination with our customers' therapies.

While some of our customers will be using our products with established, approved therapies, in many instances, the benefits of our customers' therapies as injectable therapies is either unproven or has only been proven in limited circumstances. Our ability to generate revenue from our products will depend heavily on the successful development, commercialization and sales of our customers' therapies, which is subject to many potential risks. For example, data developed in clinical trials or following the commercialization of our customers' therapies may show that such therapies do not prove to be effective treatments for the targets they are being designed to act against (or as effective as other treatments available). In clinical trials or following commercialization, it may be shown that our customers' therapies interact with human biological systems in unforeseen, ineffective or harmful ways. If our customers' therapies are associated with undesirable side effects or have characteristics that are unexpected, our customers may need to abandon clinical development or discontinue commercial sales or limit clinical development or sales to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. As a result of these and other risks described herein that are inherent in the development and sale of therapeutic agents, our customers may never successfully develop or successfully commercialize their therapies or the commercialization of our customers' therapies may be abandoned or severely limited, which may limit our profitability with respect to such customers, and we may not be successful in achieving commercial scale production and sales of our injectable drug delivery systems in combination with our customers' therapies.

Many of the injectable therapies being targeted for use with our products are not approved, but are in various phases of clinical development. These injectable therapies may be independently terminated by our customers prior to submission of a regulatory filing or even after our customers receive regulatory approval, resulting in the cessation of any revenue associated with that contract or program.

We work with pharmaceutical and biotechnology companies who are targeting the use of our products with a variety of injectable therapies. While some of our customers have approved therapies, many of our customers' injectable therapies are not approved, and are in various phases of clinical development. None of our customers with approved therapies has received regulatory clearance or approval from the FDA or a foreign regulatory authority for the commercial sale of a drug-device combination product that incorporates its approved therapy and one of our products. Typically, we become associated with pipeline therapies when they are in Phase II or Phase III clinical trials. On some occasions, especially relating to specialized or novel requirements for the delivery of an injectable therapy, we may become involved with a therapy in pre-clinical development or Phase I clinical trials. The clinical development of these pipeline therapies can be terminated by our customers at any stage. Furthermore, our customers could obtain regulatory approval for their injectable therapies and their drug-device combination products that include our product, and decide for business reasons not to market and sell their drug-device combination product. Prior investments we have made in manufacturing capacity or research and development will then not result in the generation of revenue that would have previously been anticipated through our customers' regulatory approval, launch and post-market sales of the drug-device combination product within target domestic and international markets.

Our customers may terminate their contracts or cease doing business with us in the event of a breach by us, for strategic reasons or, in some cases, for no reason.

While the term of our customer contracts may be for up to 15 years, our customers may decide to terminate their contracts or cease doing business with us in the event of a breach by us, for strategic reasons or, in some cases, for no reason. In such event, we may not receive associated payments or revenue from such customer or

under the relevant contract and we may not be able to recoup investments we have made in manufacturing capacity or research and development in connection with such customer or customer contract. Accordingly, if our customers terminate their contracts with us, it could have a material adverse impact on our business, prospects, results of operations, cash flows and financial condition.

Our commercial success depends upon the attainment of significant market acceptance of our customers' product candidates, if approved, among physicians, patients, healthcare payers or the medical community.

Even if our customers obtain regulatory approval for their product candidates, their product candidates may not gain sufficient levels of market acceptance among physicians, healthcare payers, patients or the medical community to make them commercially feasible. Market acceptance of our customers' product candidates, if they receive approval, depends on a number of factors, including the:

- efficacy and safety of our customers' product candidates;
- clinical indications for which their product candidates are approved;
- acceptance by physicians, patients and the medical community of their product candidates as a safe and effective treatment;
- potential and perceived advantages of their product candidates over alternative treatments;
- safety of their product candidates seen in a broader patient group, including their use outside the approved indications should physicians choose to prescribe for such uses;
- prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- timing of market introduction of their product candidates as well as competitive products;
- cost of treatment in relation to alternative treatments;
- availability of coverage and adequate reimbursement and pricing by third-party payers and government authorities;
- relative convenience and ease of administration; and
- effectiveness of their sales and marketing efforts.

If our customers' product candidates are approved but fail to achieve market acceptance among physicians, patients or healthcare payers, we may not be able to generate anticipated revenue. This may limit our ability to generate anticipated revenue from our prior investment in assembly lines and other resources. Moreover, even if we achieve commercial scale production and sales of our injectable drug delivery systems in combination with our customers' injectable therapies, such customers may face indirect competition from companies who develop and market other brand name, biosimilar or generic injectable therapies as well as alternative treatments and delivery methods that compete with our customers' drug-device combination products that utilize our products, which may have a material adverse effect on our results of operations, our financial condition and/or cash flows.

Most brand name injectable therapies will face future competition from generic or biosimilar therapies, which could significantly reduce their commercial viability.

Brand name injectable therapies will usually become exposed to competition from generic or biosimilar rivals at some time after their regulatory approval and commercial launch. The average selling price and market share of brand name injectable therapies can be significantly diminished following the introduction of generic or biosimilar competition. These factors may result in our customers using our products with their brand name injectable therapies seeking to withdraw such injectable therapy from the market, or change market tactics in a way that makes the use of our products cost prohibitive. This may result in the termination of supply contracts and the significant loss of revenue.

Our debt obligations include covenants restricting our business which may adversely affect us.

On March 12, 2014, Unilife Medical Solutions, Inc., a wholly owned subsidiary of the Company, or the Borrower, entered into a Credit Agreement with ROS Acquisition Offshore LP, or the Lender or ROS, as amended by the First Amendment to the Credit Agreement, dated September 30, 2014, and further amended by the Second Amendment to the Credit Agreement, dated June 30, 2015, or collectively referred to as the Amended OrbiMed Credit Agreement. Pursuant to and subject to the terms of the Amended OrbiMed Credit Agreement, the Lender agreed to provide term loans to the Borrower in the aggregate principal amount of up to \$60 million. The Borrower has received the full \$60 million under the Amended OrbiMed Credit Agreement. The interest rate is 9.25% plus the greater of the three month LIBO Rate (as defined in the Amended OrbiMed Credit Agreement) or 1.0%.

Unless the loan facility is otherwise terminated earlier pursuant to the terms of the Amended OrbiMed Credit Agreement, the Borrower is required to repay in full the unpaid principal amount of the loans drawn down, together with all accrued and unpaid interest thereon plus a 10.0% repayment premium on March 12, 2020. The Borrower can make voluntary repayments at any time of any unpaid principal amount of the loans, plus a 10.0% repayment premium. The Borrower must make mandatory prepayments in certain prescribed circumstances, including, without limitation, certain dispositions of assets and certain casualty events. In such events, the Borrower must prepay to Lender 100% of the net cash proceeds received.

The obligations of the Borrower under the Amended OrbiMed Credit Agreement are: (i) secured by substantially all assets of the Borrower, and (ii) guaranteed by the Company and each of its subsidiaries. Such guarantees are secured by substantially all assets of the guarantors. The security interests granted by Borrower, the Company, Unilife Cross Farm LLC, a wholly owned subsidiary of the Company, or Cross Farm, UMSL and Unitract Syringe Pty Limited, or Unitract Syringe, are evidenced by, among other things, a Pledge and Security Agreement, a Mortgage and Security Agreement and a General Security Deed.

The Amended OrbiMed Credit Agreement contains certain customary covenants, including among other things, covenants relating to financial performance, liquidity targets and the retention of certain members of management. The Amended OrbiMed Credit Agreement also contains covenants that, among other things, require us to obtain consent from the Lender prior to paying dividends, making certain investments, incurring debt or liens (with certain exceptions), changing the nature of our business, assuming or guaranteeing the indebtedness of another entity or individual, selling or otherwise disposing of a substantial portion of our assets, merging or consolidating with another entity, or issuing equity securities in excess of 40% of our outstanding shares of common stock to a person or group (within the meaning of Rule 13d-5 of the Exchange Act).

A breach of any of the covenants in the Amended OrbiMed Credit Agreement could result in a default under that agreement. Upon the occurrence of an event of default, a default interest rate of 14.25% per annum plus the greater of three-month LIBO Rate or 1.0% shall apply during the existence of a default. There is also a risk that the Lender could obtain rights to the secured assets in the event we default on our obligations under the Amended OrbiMed Credit Agreement. Additionally, the Lender could elect to declare all amounts outstanding under the Amended OrbiMed Credit Agreement to be immediately due and payable, and terminate all commitments to extend further credit. If the lender were to make such a demand for repayment, we would be unable to pay the obligation as we do not have existing facilities or sufficient cash on hand to satisfy this obligation and would need to seek alternate financing.

In addition, on October 20, 2010, Cross Farm entered into a Loan Agreement with Metro Bank, as amended in connection with the Amended OrbiMed Credit Agreement on March 12, 2015, or the Metro Bank Loan. The Metro Bank Loan is secured by a mortgage lien and a continuing security interest in Cross Farm's personal property, and contains certain customary covenants, including the maintenance of \$2.4 million of restricted cash that must remain in cash deposits (on which Metro Bank has a first priority security interest). In addition, we are required to maintain a cash balance of \$5 million inclusive of the \$2.4 million of restricted cash. Upon the

occurrence of an event of default under the agreement evidencing the Metro Bank Loan, there is a risk that Metro Bank could obtain rights to the secured assets. Additionally, Metro Bank could elect to declare all amounts outstanding under the Metro Bank Loan to be immediately due and payable.

Furthermore, on or about December 17, 2010, Keystone Redevelopment Group, LLC made a loan to Cross Farm in the original principal amount of \$2.25 million which was secured by a mortgage lien. Keystone Redevelopment Group, LLC assigned the loan and mortgage, or the Keystone/CFA Loan, to Commonwealth Financing Authority. Upon the occurrence of an event of default under the agreements evidencing the Keystone/CFA Loan, there is a risk that Commonwealth Financing Authority could obtain rights to the mortgaged property.

There are cross-defaults in the Amended OrbiMed Credit Agreement, Metro Bank Loan and Keystone/CFA Loan, so that a default under one agreement could trigger a default under the others. Metro Bank, the Lender under the Amended OrbiMed Credit Agreement, Keystone Redevelopment Group, LLC and Commonwealth Financing Authority are parties to an intercreditor agreement.

We may face significant uncertainty in the industry due to government healthcare reform.

The healthcare industry in the United States is subject to fundamental changes due to the ongoing healthcare reform and the political, economic and regulatory influences. In March 2010, comprehensive healthcare reform legislation was signed into law in the United States through the passage of the Patient Protection and Affordable Health Care Act and the Health Care and Education Reconciliation Act. Among other initiatives, the legislation provides for a 2.3% annual excise tax on the sales of certain medical devices in the United States, commencing in January 2013. A manufacturer of a taxable medical device may, in certain circumstances, sell a taxable medical device tax-free for use by the purchaser for further manufacture (or for resale by the purchaser to a second purchaser for further manufacture), or for export (or for resale for export). We believe that the 2.3% annual excise tax is not applicable to us because our products are sold to our customers as components for further assembly by our customers. However, we cannot give assurances that the U.S. Internal Revenue Service will treat the sale of our products to our customers for use in their drug-device combination products as tax-free sales. Accordingly, this enacted excise tax may adversely affect our operating expenses and results of operations. In addition, various healthcare reform proposals have also emerged at the state level. We cannot predict with certainty what healthcare initiatives, if any, will be implemented at the state level, or what the ultimate effect of federal healthcare reform or any future legislation or regulation may have on us or on our customers' purchasing decisions regarding our products and services.

Some companies we may utilize for the supply of components are also competitors, and they could elect to cease supply relationships with us in the future for competitive reasons.

Some companies we may utilize for the supply of components for our proprietary product platforms also develop and market their own products that compete with ours. These companies may elect to cease supply relationships with us in the future for competitive reasons. This may disrupt our supply chain, cause difficulties in the qualification of new sources of supply and impair our ability to supply customer orders. Such events may have a material adverse effect on our results of operations, our financial condition and/or cash flows.

The injectable drug delivery systems industry is very competitive.

The market for injectable drug delivery systems is highly competitive. We compete against many companies, both public and private, that range in size from small, highly focused businesses to large diversified multinational manufacturers of medical devices and healthcare equipment. Our larger competitors have greater financial and human resources, distribution channels and sales and marketing capabilities than we do which may provide them a competitive advantage in acquiring new customers.

Additionally, while our customizable platforms and multi-source strategy for components and raw materials provides us significant differentiation in the medical device markets, it also makes supplier relationships a key aspect of our business model. Many of our competitors are vertically integrated and may source their own raw materials and/or produce their own commodity components such as glass barrels or elastomers. As such, these competitors have greater control over the supply of these components and are therefore not subject to the same supply chain risks to which we are subject. Furthermore, because we do not produce these commodity components ourselves, we may need to purchase certain components from commodity component suppliers who are also our device competitors. Such supplier-competitors may have a disincentive to meet our supply chain needs on terms that are favorable to us.

We are also subject to competition from our customers. In particular, our customers can decide to develop their own injectable drug delivery systems internally. Moreover, we may face indirect competition from companies who develop and market alternative treatments and delivery methods that compete with our customers' drug-device combination products that utilize our products.

Our ability to compete effectively depends upon our ability to distinguish our company and our products from our competitors and their products. Factors affecting our competitive position include, for example, product design and performance, pricing of our services and products, product safety, sales, marketing and distribution capabilities, success and timing of new product development and introductions and intellectual property protection.

We may be unable to protect our intellectual property rights or may infringe on the intellectual property rights of others.

Our success depends in part on our ability to obtain and maintain protection in the United States and other countries of the intellectual property relating to or incorporated into our technology and products. Though granted patents expire at varying dates based on the filing date of the related application, the life of patents relating to our product platforms extends through calendar year 2035. Pending and/or future filed patent applications covering relevant advancements in these technologies could extend well beyond that time period once granted. Our pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will provide us with any competitive advantage or adequate protection. In particular, the injectable drug delivery systems which we are developing and for which we have filed patent applications are relatively new inventions, and we cannot be sure that we will be able to obtain patents on these inventions. Our issued and future patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar technology or products or limit the length of terms of patent protection we may have for our technology or products. Changes in patent laws or their interpretation in the United States and other countries could also diminish the value of our intellectual property or narrow the scope of our patent protection. In addition, the legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing technology or products similar or identical to ours. In order to preserve and enforce our patent and other intellectual property rights, we may need to make claims or file lawsuits against third parties. This can entail significant costs to us and divert our management's attention from developing and commercializing our technology or products.

There also can be no assurance that third parties will not assert that our technology or products infringe their patent or other intellectual property rights. Any claims, with or without merit, could be time-consuming, result in costly litigation, divert the efforts of our technical and management personnel or require us to pay substantial damages. If we are unsuccessful in defending ourselves against these types of claims, we may be required to do one or more of the following:

- stop, delay or abandon our ongoing or planned commercialization of the product that is the subject of the suit;

- attempt to obtain a license to sell or use the relevant technology or substitute technology, which license may not be available on reasonable terms or at all;
- redesign the product that uses the relevant technology; or
- pay substantial damages which could adversely impact our financial condition and ability to execute our business plan and operations.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patented technology, we rely on our unpatented proprietary technology, trade secrets, processes and know-how. We generally seek to protect this information by confidentiality agreements with our employees, consultants, scientific advisors, contractors and third parties. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors. To the extent that our employees, consultants, scientific advisors or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

We, as an FDA-registered medical device manufacturer and component supplier to our customers, are required to comply with cGMP for any products we supply to our customers for clinical or commercial use. If we fail to comply with cGMP for our manufacturing facility, our business and our results of operations would be harmed.

Our QMS is regularly audited by regulatory authorities for compliance with the requirements of, and certified to, ISO 13485, Medical Devices – Quality Management Systems – Requirements, for regulatory purposes, which is equivalent to QSR for FDA compliance. As an FDA registered medical device manufacturer, we are periodically audited by the FDA pursuant to the QSRs and cGMP with the last audit occurring in 2013 where there were no formal findings. In addition, our QMS is regularly audited by existing and prospective customers.

If we do not continue to have our QMS in compliance with ISO certifications or receive major non-conformances by the FDA or other foreign regulatory authorities during audits of our QSRs and cGMP, we may experience regulatory related delays as a result. If we do not comply with cGMP when supplying any products to our customers for clinical or commercial use, our failure could have a material adverse impact on our business, prospects, results of operations, cash flows and financial condition.

If we experience interruptions in our manufacturing operations, our business will suffer.

We currently manufacture our products at our York, Pennsylvania facility, with no alternate facilities available. If we were to experience a manufacturing disruption as a result of damage or destruction of the building, equipment failure, acts of God or other force majeure events, our ability to satisfy our obligations to our customers would be adversely affected, which would harm our business and our results of operations.

The sale of any of our proprietary product platforms could be stopped, delayed or made less profitable if our manufacturing facility fails to provide us with sufficient quantities of our proprietary product platforms or fails to do so at acceptable quality levels or prices and in a timely manner.

To manufacture our proprietary product platforms in the quantities and at the price that we believe would be required to meet anticipated market demand of future customers, or in the event of increased orders from our current customers, we may need to increase manufacturing capacity, which could involve typical scale-up challenges. In addition, any expansion to our existing commercial-scale manufacturing capabilities may require us to invest substantial funds and hire and retain technical personnel who have the necessary manufacturing experience. We may not successfully complete any manufacturing scale-up activities required to increase existing manufacturing capabilities in a timely manner, or at all.

Product defects could adversely affect the results of our operations.

The design, manufacture and marketing of our products involve certain inherent risks. Manufacturing or design defects, unanticipated use of our products, or inadequate disclosure of risks relating to the use of the product can lead to injury or other adverse events. These events could lead to recalls or safety alerts relating to our products (either voluntary or required by the FDA or similar governmental authorities in other countries), and could result, in certain cases, in the removal of a product from the market. Any recall could result in significant costs, the loss of a customer, negative publicity and damage to our reputation that could reduce demand for our products. Personal injuries relating to the use of our products can also result in product liability claims being brought against us. In some circumstances, such adverse events could also cause delays in the launch of new products.

Because our proprietary product platforms, in connection with our customers' injectable therapies, will be drug-device combination products, we also face additional risks of recalls that could be caused by our customers' therapies. Any such recall could similarly result in significant costs, negative publicity and damage to our reputation, even if caused by a customer's products. We may also realize significant costs and delay in finding a substitute customer to sell into the affected market, if one can be found at all.

We may be sued for product liability, which could adversely affect our business.

The design, manufacture and marketing of our products carry a significant risk of product liability claims. We may be held liable if any product we develop and sell to our customers causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or consumer use. In addition, since our products will be used in our customers' drug-device combination products, we may be sued for product liability even if the claimed injury is caused by our customers' injectable therapies and not our products. We carry product liability insurance in the amount of \$10 million. However, if there were to be product liability claims against us, our insurance may be insufficient to cover the expense of defending against such claims, or may be insufficient to pay or settle such claims. Furthermore, we may be unable to obtain adequate product liability insurance coverage for sales of any of our products or our customers' drug-device combination products that utilize our products. If such insurance is insufficient to protect us, our results of operations will suffer. If any product liability claim is made against us, our reputation and future sales will be damaged, even if we have adequate insurance coverage. We also intend to seek product liability insurance for any products that we may develop or acquire and any of our products that are used in combination with our customers' injectable therapies in the future. There is no guarantee that such coverage will be available when we seek it or at a reasonable cost to us.

Our relationships with customers will be subject to applicable state, federal and healthcare laws and regulations, which could result in criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payers will play a primary role in the recommendation and prescription of any drug-device combination products for which our customers obtain marketing approval. Our future arrangements with our customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect the business or financial arrangements and relationships through which we would market, sell and distribute our products. Although we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payers, federal and state healthcare laws and regulations may be applicable to our business.

Efforts to ensure that our business arrangements with third parties are compliant with applicable healthcare laws and regulations will involve the expenditure of appropriate, and possibly significant, resources. Nonetheless, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment and the curtailment or restructuring of our operations.

We cannot give any assurance that we will be able to complete the development and sale of new injectable drug delivery systems in response to changes in medical technologies, industry standards and the emerging needs of pharmaceutical and biotechnology companies.

A significant element of our strategy focuses on developing a broad portfolio of injectable drug delivery systems that deliver greater benefits to pharmaceutical and biotechnology companies, and ultimately health-care providers and patients. These new injectable drug delivery systems, including customized products, are a response to changes in medical technologies, industry standards and the emerging needs of pharmaceutical and biotechnology companies. Other device companies, and pharmaceutical and biotechnology companies, are also attempting to develop alternative therapies or drug administration systems such as needle-free or intradermal injection technology for the treatment or prevention of various diseases. Our success will depend on our ability to continue developing and selling new injectable drug delivery systems to meet the changing conditions of the marketplace. The development of these injectable drug delivery systems requires significant research and development and expenditures of capital. There can be no assurance that our development efforts will result in successful new products that can compete with new or improved products, processes or technologies by other companies.

We may encounter difficulties managing our growth, which could materially harm our business.

We have rapidly expanded our operations, including our research and development, product development, regulatory, manufacturing, sales, marketing and administrative functions. This expansion has placed, and is expected to continue to place, a significant strain on our management, operational and financial resources. To manage our growth and to develop and sell our products will require continued investment in procedures and systems relating to operational, financial and quality control processes, and continue to expand, train and manage our employee base. In addition, we will need to manage relationships with various manufacturers, suppliers, customers and other organizations. Our failure to accomplish any of these tasks could materially harm our business.

We will continue to incur significant costs as a result of being a public company in both the United States and Australia.

We are subject to the periodic reporting requirements of the Exchange Act. Being a public reporting company in the United States entails significant expense, including costs required for us to comply with the Sarbanes-Oxley Act of 2002. In addition, because our shares of common stock are also listed on the ASX, in the form of CDIs, we are also required to file financial information and make certain other filings with the ASX. Our status as a reporting company in both the United States and Australia makes some activities more time-consuming and costly and causes us to incur legal, accounting and other expenses that are higher than those that are typically incurred by companies that are subject to reporting requirements in only one jurisdiction.

The costs of raw materials have a significant impact on the level of expenses that we incur. If the prices of raw materials and related factors such as energy prices increase, and if we cannot pass those price increases on to our customers, our results of operations and financial condition would suffer.

We use a number of raw materials including polymer plastics. The prices of many of these raw materials, such as those sourced from petroleum-based raw materials, are cyclical and volatile. While we would generally attempt to pass along increased costs to our customers in the form of sales price increases, we might not be able to do so for competitive or contract-related reasons or otherwise. If we cannot set or adjust our prices to reflect the costs of our raw materials, our results of operations and our financial condition will suffer.

Disruptions in the supply of key raw materials and difficulties in the supplier qualification process could adversely impact our operations.

We employ a supply chain management strategy which seeks to source components and materials from a number of established third party companies. Where possible, we seek to establish more than one contract for the

supply of a particular component, material or service. However, there is a risk that our supply lines may be interrupted in the event of a supplier production problem, material recall or financial difficulties. If one of our suppliers is unable to supply materials required for production of our products or our strategies for managing these risks are unsuccessful, we may be unable to complete the production of sufficient quantities of product to fulfill customer orders, or complete the qualification of new replacement materials for some programs in time to meet future production requirements. Prolonged disruptions in the supply of any of our key raw materials or components, and difficulty in completing qualification of new sources of supply or in implementing the use of replacement materials or new sources of supply could have a material adverse effect on our results of operations, our financial condition or cash flows.

We are subject to regulations related to conflict minerals, which could adversely impact our operations.

Pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act, the SEC issued final rules regarding disclosure of the use of tantalum, tin, and tungsten (or their ores) and gold, or conflict minerals, which are mined from the Democratic Republic of the Congo and adjoining countries. We are now required to report on the source of any conflict minerals used in our products, as well as the process we use to determine the source of such materials. We have and will continue to incur expenses as we work with our suppliers to remain in compliance with these requirements and compliance with these requirements could adversely affect the sourcing, supply, and pricing of our raw materials. We may face reputational challenges if we determine that certain of our products contain minerals not determined to be conflict free or if we are unable to sufficiently verify the origins for all conflict minerals used in our products. In addition, we may encounter challenges satisfying customers who require that all of the components of our products be certified as conflict free. If we are unable to comply with these requirements, it could have a material adverse effect on our results of operations, our financial condition or cash flows.

Impairment of our goodwill, which represents a significant portion of our total assets, would adversely affect our operating results and we may never realize the full value of our goodwill.

As of June 30, 2015, we had \$9.7 million of goodwill on our balance sheet, which represented 10.3% of our total assets. We recorded this goodwill primarily from our historical acquisition activities. Goodwill is subject to, at a minimum, an annual impairment assessment of its carrying value. Any material impairment of our goodwill would likely have a material adverse impact on our results of operations.

Global economic conditions and risks could adversely affect our business and operations.

In recent years, the commercial and financial markets have been faced with very challenging global economic conditions, particularly in the United States and Europe. Many of our customers and potential customers are international pharmaceutical and biotechnology companies based in the United States or in Europe. Deterioration in the global economic environment, particularly in those regions, may result in decreased demand for our products and services, downward pressure on the prices for our products, longer sales cycles, and slower adoption of new technologies. A weakening of macroeconomic conditions may also adversely affect our suppliers based in the United States or Europe, which could result in interruptions in supply in the future. Similarly, this international exposure of our business may subject us to less intellectual property protection in some countries outside the U.S., non-U.S. regulatory requirements, trade protection measures and import or export licensing requirements. There can be no assurance that a deterioration of economic conditions in international markets will not adversely affect our future results. Moreover, changes in foreign currency exchange rates can affect the value of our assets and liabilities, and the amount of our revenue and expenses. We do not currently try to mitigate our exposure to currency exchange rate risks by using hedging transactions. We cannot predict future changes in foreign currency exchange rates, and as a result, we may suffer losses as a result of future fluctuations.

Changes in reimbursement practices of third-party payers could affect the demand for some of our products and the prices at which they are sold and adversely affect our financial condition and results of operations.

Sales of our insulin delivery systems may depend, in part, on the extent to which healthcare providers and facilities are reimbursed by government authorities, private insurers and other third-party payers for the costs of our products. The coverage policies and reimbursement levels of third-party payers, which can vary among public and private sources and by country, may affect which products customers purchase and the prices they are willing to pay for those products in a particular jurisdiction. Reimbursement rates can also affect the acceptance rate of new technologies and products. Legislative or administrative reforms to reimbursement systems in the United States or abroad, or changes in reimbursement rates by private payers, could adversely affect customer demand or the price customers are willing to pay for our products, which could in turn adversely impact our financial condition and results of operations.

Failure to successfully implement, manage and/or integrate critical information systems, disruption of these systems or material breaches of the security of systems involved in our operations may adversely affect our business and customer relationships.

We rely on our information technology systems, or ITS, to process, transmit, and store electronic information in our day-to-day operations. Some of the information stored is commercially sensitive, such as information regarding our customers and our intellectual property. We actively update our ITS to ensure protection and to prevent redundancy. However, electronic attacks, system crashes, destruction from unexpected tragedies and unauthorized access is a common risk to all ITS in today's business world. There can be no assurances that our protective measures will prevent the events mentioned or other similar instances which could have a significant impact on our business and customer relationships.

We depend on our executive officers and key personnel and the loss of them could adversely affect our business.

Our success depends upon the efforts and abilities of our executive officers and other key personnel, particularly Mr. Alan Shortall, our Chairman and Chief Executive Officer, and Dr. Ramin Mojdeh, our President and Chief Operating Officer, to provide strategic direction, manage our operations and maintain a cohesive and stable environment. Although we have employment agreements with Mr. Shortall and Dr. Mojdeh, as well as incentive compensation plans that provide various economic incentives for them to remain with us, these agreements and incentives may not be sufficient to retain them. Our ability to operate successfully and manage our potential future growth also depends significantly upon our ability to attract, retain and motivate highly skilled and qualified research, technical, clinical, regulatory, sales, marketing, managerial and financial personnel. We face intense competition for such personnel, and we may not be able to attract, retain and motivate these individuals. The loss of our executive officers or other key personnel for any reason or our inability to hire, retain and motivate additional qualified personnel in the future could prevent us from sustaining or growing our business.

Risk Factors Related to Our Shares of Common Stock

The trading price of our shares of common stock may fluctuate significantly.

The price of our shares of common stock may be volatile, which means that it could decline substantially within a short period of time. The trading price of the shares may fluctuate, and investors may experience a decrease in the value of the shares that they hold, sometimes regardless of our operating performance or prospects. The trading price of our common stock could fluctuate significantly for many reasons, including the following:

- future announcements concerning our business and that of our competitors including in particular, the progress of our sales of our injectable drug delivery systems;

- regulatory developments;
- quarterly variations in operating results;
- negative reporting about us in the press;
- introduction of new products or changes in product pricing policies by us or our competitors;
- acquisition or loss of significant customers, distributors or suppliers;
- business acquisitions or divestitures;
- fluctuations of investor interest in the injectable drug delivery systems industry; and
- fluctuations in the economy, world political events or general market conditions.

If there are substantial sales of our shares of common stock, our share price could decline.

As of September 4, 2015, we had 136,123,818 shares of common stock outstanding. All of those shares of common stock other than 15,388,729 shares held by our affiliates are freely tradable under the Securities Act. Shares held by our affiliates are eligible for resale pursuant to Rule 144. If our stockholders sell a large number of shares of common stock, or the short interest position increases significantly, the market may perceive that our stockholders might sell a large number of shares, which could cause the price of our common stock to decline significantly.

In addition, as of September 4, 2015, 3,432,330 shares of our common stock are subject to outstanding stock options and warrants. We have registered the shares issuable upon the exercise of options granted under our Amended and Restated 2009 Stock Incentive Plan. In addition, we have effective registration statements covering the resale of shares of our common stock that are issuable upon the exercise of our remaining options and warrants. If these options and warrants are exercised and the holders choose to sell their shares, such sales could have an adverse effect on the market price of our common stock.

We do not intend to pay cash dividends in the foreseeable future.

For the foreseeable future, we do not intend to declare or pay any dividends on our common stock. We intend to retain our earnings, if any, to finance the development and expansion of our business and product lines. Any future decision to declare or pay dividends will be made by our board of directors and will depend upon a number of factors including our financial condition and results of operations. In addition, under our current bank financing agreements, we are not permitted to pay cash dividends without the prior written consent of the lender.

We may be subject to arbitrage risks.

Investors may seek to profit by exploiting the difference, if any, in the price of our shares of common stock on the NASDAQ and our CDIs on the ASX. Such arbitrage activities could cause our stock price in the market with the higher value to decrease to the price set by the market with the lower value.

Our certificate of incorporation, bylaws, and the Delaware General Corporation Law may delay or deter a change of control transaction.

Certain provisions of our certificate of incorporation and bylaws may have the effect of deterring takeovers, such as those provisions authorizing our board of directors to issue, from time to time, any series of preferred stock and fix the designation, powers, preferences and rights of the shares of such series of preferred stock; prohibiting stockholders from acting by written consent in lieu of a meeting; requiring advance notice of stockholder intention to put forth director nominees or bring up other business at a stockholders' meeting; prohibiting stockholders from calling a special meeting of stockholders; requiring a 66 2/3% majority

stockholder approval in order for stockholders to amend our bylaws or adopt new bylaws; and providing that, subject to the rights of preferred shares, the number of directors is to be fixed exclusively by our board of directors. Section 203 of the Delaware General Corporation Law, from which we did not elect to opt out, provides that if a holder acquires 15% or more of our stock without prior approval of our board of directors, that holder will be subject to certain restrictions on its ability to acquire us within three years. These provisions may delay or deter a change of control of us, and could limit the price that investors might be willing to pay in the future for shares of our common stock.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our 165,000 square foot global headquarters and manufacturing facility is located on 38 acres of land in York, Pennsylvania. The facility includes 110,000 square feet of production space and 54,000 square feet of office space. The property is subject to a mortgage held by Metro Bank.

We also lease 52,000 square feet of office space in King of Prussia, Pennsylvania to support our research and development activities. The initial term of the King of Prussia lease runs to June 30, 2022. Our annual occupancy expense under this lease is \$1.2 million.

We also lease 1,100 square feet of office space in Sydney, Australia on a month-to-month basis, which is used for certain finance and administrative operations.

Item 3. Legal Proceedings

Talbot Smith v. Unilife Corporation, et al.

A former employee, Talbot Smith, who was terminated for cause by Unilife, filed a civil complaint in the United States District Court of the Eastern District of Pennsylvania on August 30, 2013, and an amended complaint on March 5, 2014, alleging that he was wrongly terminated in retaliation for making allegations about the Company's compliance practices. We and various third parties, including law firms and regulatory consulting firms, investigated the allegations made by Mr. Smith and determined that his allegations were without merit, and the Company brought counterclaims against Mr. Smith. Discovery concluded and in February 2015 we filed our motions for summary judgment with the District Court, seeking entry of judgment in favor of the Company on the claims brought by Mr. Smith against the Company, and entry of judgment in favor of the Company on the claims brought by the Company against Mr. Smith.

Following the discovery process and while the Company's motions for summary judgment were pending before the District Court, on August 18, 2015, Mr. Smith dismissed his claims against the Company with prejudice.

In connection with the resolution and dismissal of the action, Mr. Smith agreed to make a payment to the Company to settle the Company's claims against him. Mr. Smith received no payment as part of the resolution and dismissal of his claims against the Company, and his attorney received a reduced portion of her fees from the Company's insurer. The entire action in the District Court has been dismissed with prejudice and the matter is now concluded.

Cambridge Retirement System

On January 8, 2014, we were served with a derivative complaint filed in the Delaware Chancery Court by Cambridge Retirement System, a purported stockholder of ours, against our board of directors to recover allegedly “excessive and wasteful” compensation paid to the non-executive directors since 2010. We believe that these allegations are baseless and without merit and we and the directors are defending ourselves vigorously. In February 2014, we filed a motion to dismiss the complaint in lieu of an answer. On June 26, 2014, the Court granted our motion to dismiss with respect to the directors’ equity grants, but denied the motion with respect to their cash compensation. We filed an answer to the remaining claims on July 11, 2014. On June 4, 2015, the parties entered into a Memorandum of Understanding agreeing to the basic terms of a non-monetary settlement of the action. The parties are negotiating the final terms of a stipulated settlement to be submitted to the Court for approval.

We do not believe there will be any material impact to us or our business as a result of this matter.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Commencing February 16, 2010, our shares of common stock began trading on the Global Market of The NASDAQ Stock Market LLC, or the NASDAQ Global Market, under the symbol "UNIS". Our shares of common stock have also traded in the form of CDIs representing one-sixth of a share of our common stock, on the ASX under the symbol "UNS" since January 18, 2010. Prior to that date, the ordinary shares of our predecessor UMSL were traded on the ASX under the symbol "UNI".

The following table sets forth, for the periods indicated, the high and low prices for our common stock on the NASDAQ Global Market:

Period	High	Low
Fiscal Year 2015:		
First Quarter	3.31	2.20
Second Quarter	4.10	2.00
Third Quarter	4.90	3.23
Fourth Quarter	4.13	2.00
Fiscal Year 2014:		
First Quarter	3.78	2.61
Second Quarter	5.10	2.55
Third Quarter	5.80	3.77
Fourth Quarter	4.23	2.66

Holders

As of September 4, 2015, we had 136,123,818 shares of common stock outstanding, and there were 376 holders of record of our common stock, including CHES Depositary Nominees which held shares of our common stock on behalf of 7,834 CDI holders. The closing sales price for our common stock on September 4, 2015 was \$1.34 as reported by the NASDAQ Global Market.

Dividends

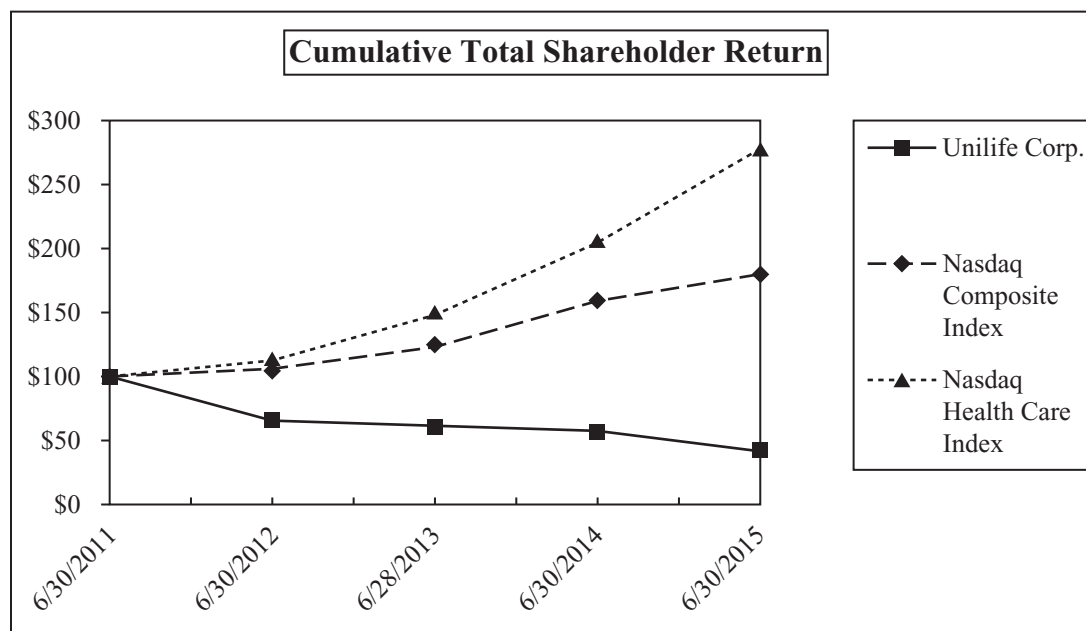
We currently intend to retain any earnings to finance research and development and the operation and expansion of our business and do not anticipate paying any cash dividends for the foreseeable future. The declaration and payment of any dividends in the future by us will be subject to the sole discretion of our board of directors and will depend upon many factors, including our financial condition, earnings, capital requirements of our operating subsidiaries, covenants associated with certain of our debt obligations, legal requirements, regulatory constraints and other factors deemed relevant by our board of directors. Moreover, if we determine to pay any dividend in the future, there can be no assurance that we will continue to pay such dividends. In addition, under our bank financing agreements, we are not permitted to pay cash dividends without the prior written consent of the lender.

Issuer Purchases of Equity Securities

We did not purchase any shares of our common stock during the three months ended June 30, 2015.

Performance Graph

The performance graph shown below compares the change in cumulative total stockholder return on shares of common stock with the NASDAQ Stock Market Index (US) and the Nasdaq Health Care Index (US) from February 16, 2010, our first day of trading on the NASDAQ Global Market, through fiscal year 2015. The graph sets the beginning value of shares of common stock and the indices at \$100, and assumes that all quarterly dividends were reinvested at the time of payment. This graph does not forecast future performance of shares of common stock.



	6/30/2011	6/30/2012	6/28/2013	6/30/2014	6/30/2015
Unilife Corp.	100.00	65.25	61.20	57.14	41.51
Nasdaq Composite Index	100.00	105.82	122.71	158.94	179.80
Nasdaq Health Care Index	100.00	112.44	147.95	204.25	277.80

Item 6. Selected Financial Data

The following table presents our selected consolidated financial data as of and for each of the fiscal years in the five-year period ended June 30, 2015. The statements of operations data for the fiscal years 2015, 2014 and 2013 and the balance sheet data as of June 30, 2015 and 2014 have been derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. All such data should be read in conjunction with the information under “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and our consolidated financial statements and the related notes thereto included elsewhere in this report. The statements of operations data for the fiscal years ended June 30, 2012 and 2011 and the balance sheet data as of June 30, 2013, 2012 and 2011 have been derived from our audited consolidated financial statements not included in this Annual Report on Form 10-K. Historical results are not necessarily indicative of the results to be expected in the future.

	Fiscal Years Ended June 30,				
	2015	2014	2013	2012	2011
	(In thousands, except share data)				
Statements of Operations Data:					
Revenue(a)	\$ 13,158	\$ 14,689	\$ 2,743	\$ 5,519	\$ 6,650
Net loss	(90,849)	(57,899)	(63,198)	(52,302)	(40,682)
Basic and diluted net loss per share	(0.81)	(0.59)	(0.78)	(0.78)	(0.70)
Balance Sheet Data:					
Total assets	\$ 94,129	\$ 81,768	\$ 68,401	\$ 82,308	\$ 89,478
Long-term debt, including current portion	80,435	55,448	23,871	28,765	22,687

- (a) Includes \$2.3 million, \$2.6 million, \$4.1 million, and \$3.9 million in connection with our former exclusive licensing agreement and our industrialization agreement with Sanofi in the fiscal years ended June 30, 2014, 2013, 2012 and 2011, respectively.

Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. This discussion and analysis includes certain forward-looking statements that involve risks, uncertainties and assumptions. You should review the “Risk Factors” section of this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by such forward-looking statements. See “Cautionary Note Regarding Forward-Looking Information” at the beginning of this report. References to our fiscal year refer to the fiscal year ending June 30.

Overview

We are a designer, manufacturer and supplier of innovative injectable drug delivery systems that can enhance and differentiate the injectable therapies of our customers. We have a broad portfolio of proprietary product platforms, including pre-filled syringes, wearable injectors, insulin delivery systems, disposable and reusable auto-injectors, drug reconstitution delivery systems, ocular delivery systems and other systems for the targeted delivery of injectable therapies. Products within each platform are differentiated from competitors’ products with a series of innovative features designed to optimize the safe, simple and convenient administration of an injectable therapy. We sell our products directly to pharmaceutical and biotechnology companies who incorporate them into the drug-device combination product that is supplied pre-filled and ready for administration by end-users such as health-care providers or patients. Products within each of our platforms can be customized by us to address specific customer, therapy, patient and/or commercial requirements.

Our growing base of customers includes Sanofi, MedImmune, AbbVie, Novartis and Hikma. In addition to the filling, assembly and/or packaging of our product with an injectable therapy, our customers are also responsible for the regulatory approval, sale and marketing of their final drug-device combination product. With certain of our devices that we could sell directly to healthcare providers or end users without having them pre-filled with a drug by a pharmaceutical company, we would be responsible for the regulatory approval, sale and marketing of the final device. In addition to product sales, we can generate revenue from customization programs, upfront fees and exclusivity or royalty payments.

Key Factors Affecting Performance and Financial Condition

We have entered into several agreements with our customers, including customers with whom we have entered into a customization or supply agreement and customers with whom we have entered into preliminary agreements such as letters of intent. The customization, industrialization and development fees and other payments received from customers in connection with these agreements and development programs accounted for the majority of our revenue during the year ended June 30, 2015. We also increased expenses during the year ended June 30, 2015 as a result of investments in expanding our manufacturing capacity and increased research and development efforts, both in response to increasing demand from our customers for our products and services.

Longer customer development timelines and increases in capital expenses and headcount have impacted us from a liquidity standpoint. Historically, we have funded our operations primarily from a combination of term loans, equity issuances, borrowings under our bank mortgages, and payments from various customers. In recent years we have addressed our capital needs through the use of an “At-The-Market” equity offering, pursuant to which we, from time to time, issued and sold shares of common stock having an aggregate offering price of \$45.0 million, customization, industrialization and development fees received from our customers, and our debt financing from an affiliate of OrbiMed Advisors, or OrbiMed, in March 2014. In February 2015, we issued 12,650,000 shares of common stock and raised \$44.7 million, net of issuance costs, through an underwritten registered public offering. On July 29, 2015, we entered into the Sales Agreement with Cantor, pursuant to which we may, from time to time,

issue and sell shares of common stock, having an aggregate offering price of up to \$25.0 million. To date, we have issued 2,870,689 shares for net proceeds of \$3.8 million under the Sales Agreement. During July 2015, we entered into the Purchase Agreement with LPC, pursuant to which we have the right to sell, from time to time, to LPC up to \$45.0 million in shares of our common stock, subject to certain limitations and conditions set forth in the Purchase Agreement. The purchase price of shares of Common Stock pursuant to the Purchase Agreement will be based on the prevailing market price at the time of sale as set forth in the Purchase Agreement. In connection with the entry into the Purchase Agreement, we issued 3,244,650 shares of common stock to LPC and received net proceeds of approximately \$4.8 million after expenses.

Revenue

Our revenue is currently generated from customization, industrialization, licensing and development fees (many of which are recognized on the milestone basis of accounting). Customization, industrialization, development and licensing fees accounted for substantially all of our consolidated revenue during fiscal year 2015. Product sales historically have not had a meaningful impact on our revenue, however, we expect over time they will begin to account for an increasing portion of our revenue as we increase sales to customers during fiscal year 2016.

We expect our revenue to increase over time, as we continue to deliver under our existing contracts with our customers and enter into additional agreements with new and existing customers, however, our revenue could fluctuate on a quarter to quarter basis. We also expect that our future revenue will be favorably impacted by several trends in the industry, including a shift in the focus of large pharmaceutical and biotechnology companies' product development activities to biologic therapies, an emphasis within health-care providers to patient self-administration and a growing demand for passive safety for injectable drug delivery.

Operating Expenses

Our operating expenses have increased primarily as a result of the increased research and development efforts in response to increasing demand from our customers for our products and services. We increased our cross-functional research and development teams of engineers and other staff that are dedicated to servicing existing and prospective customers. The increase in research and development costs also related to the costs of products and components supplied to existing and prospective customers to support evaluation processes and user studies that are typically undertaken prior to the anticipated signing of customer agreements. We have also continued to invest in our facilities and in capital equipment in the amount of \$16.6 million during fiscal year 2015. We completed a reconfiguration of our existing cleanroom manufacturing space at our York, Pennsylvania facility to accommodate new assembly lines for our Unifill and wearable injector products that will support scheduled customer demand during fiscal year 2016. We are also installing additional clean room manufacturing space within the existing footprint of our York facility that will accommodate additional assembly lines and related activities. Accordingly, we have secured pre-approval from York County Pennsylvania to construct an additional 100,000 square foot of production space at our York facility, which may be undertaken at some future date subject to commercial demand. We also invested in equipment to expand our manufacturing capacity for wearable injectors in response to accelerating customer demand as well as investing in the expansion of our manufacturing capabilities for additional product platforms across our broad portfolio of injectable drug delivery systems. During fiscal year 2015, we also increased headcount by 69 employees (consisting mostly of employees focused on research and development) and invested \$52.5 million to address our research and development requirements, including employee costs, equipment, materials, tooling, prototypes and outside contract services. We increased our cross-functional research and development teams of engineers and other staff that are dedicated to servicing existing and prospective customers. The increase in research and development costs also related to the costs of products and components supplied to existing and prospective customers to support evaluation processes and user studies that are typically undertaken prior to the anticipated signing of customer agreements.

Significant Developments in the Industry

We believe that recently signed customer contracts and future customer contracts expected to be signed with existing and prospective customers, as a result of ongoing discussions, could provide significant revenue growth in relation to prior periods. Known trends in the industry that we believe will have a material favorable impact on our revenue include a shift in the focus of large pharmaceutical and biotechnology companies' product development activities to biologic therapies, an emphasis within health-care providers to patient self-administration and a growing demand for passive safety for injectable drug delivery. There has been a marked shift in the product development activities of large customers toward biologic therapies, and the majority of therapies in the pipeline of large pharmaceutical and biotechnology companies are complex biologic therapies. The characteristics of many of these therapies (including, for example, large dose volumes and increased viscosity) necessitates administration by injection using innovative injectable drug delivery systems such as our products. We believe that we are well-positioned to meet what we expect to be a growing demand for innovative injectable drug delivery systems in light of the focus on biologic therapies. Concurrently with the shift toward biologic therapies is an emphasis towards patient self-administration. Patient self-administration is viewed as a growing trend in order to reduce demand pressure on the health-care system as well as reducing costs, especially for treatment of chronic illnesses. Devices suitable for self-administration of injectable therapies need to be safe and intuitive to use. We believe that many of our products, including prefilled syringes, drug reconstitution delivery systems, auto-injectors, and wearable injectors, are well suited for safe and intuitive patient self-administration of injectable therapies and that we will be able to meet the expected increase in demand for such products.

Critical Accounting Policies and Estimates

We prepare our audited consolidated financial statements in accordance with accounting principles generally accepted in the U.S., or U.S. GAAP. This requires management to make certain estimates, judgments and assumptions that could affect the amounts reported in the audited consolidated financial statements and accompanying notes. We believe there are several accounting policies that are critical to understanding our historical and future performance, as these policies affect the reported amounts of revenue and other significant areas that involve management's judgments, estimates and assumptions. These critical accounting policies and estimates have been discussed with our audit committee.

The preparation of our audited consolidated financial statements requires us to make judgments, estimates and assumptions that affect the amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, we evaluate these judgments, estimates and assumptions. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable at such time, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other independent sources. Actual results may ultimately differ from these estimates.

While there are a number of accounting policies, methods and estimates affecting our consolidated financial statements as addressed in Note 3 to our audited consolidated financial statements, areas that are particularly significant and critical include:

Revenue Recognition

We recognize revenue from industrialization and development fees, licensing fees and product sales. We recognize revenue from sales of products at the time of shipment when title passes to the customer. We recognize up front, non-refundable fees ratably over the expected life of the related agreement. Revenue from industrialization and development fees is recognized as services are rendered or upon achievement of the "at risk" substantive milestone events, which represent the culmination of the earnings process related to such events. Substantive milestones can include specific deliverables such as product design, prototype availability, user tests, manufacturing proof of principle and the various steps to complete the industrialization of the product. The terms of these contracts

provide for customer payments to be made as services are rendered or substantive milestones are achieved. We consider whether a milestone is substantive at the inception of the agreement. The consideration earned from the achievement of a milestone must meet all of the following criteria to be considered substantive:

- It is commensurate with either our performance to achieve the milestone, or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from our performance to achieve the milestone;
- It relates solely to past performance; and
- It is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

Payment terms are considered to be standard commercial terms. Revenue is recognized when each substantive milestone has been achieved and we have no future performance obligations related to the substantive milestone. Fees for completed substantive milestones which are dependent upon customer acceptance for non-refundable payment or, if paid, are refundable pending customer acceptance are recognized upon customer acceptance and the termination of refund rights.

We recognized \$13.2 million, \$14.7 million and \$2.7 million of revenue during fiscal years 2015, 2014 and 2013, respectively, as follows:

During the fiscal year 2015, we recognized \$5.1 million in revenue related to substantive milestones that were completed during the year pursuant to customer agreements to provide customization and development services, clinical support services, collaborative research activities and testing support services. Milestones completed during the year included various customization activities, device design, devices developed for use in customer evaluation testing, compatibility testing, user studies, and verification activities.

During fiscal year 2015, we recognized \$8.1 million in revenue related to services rendered on a time and materials basis, proportional performance method and/or straight-line basis over the requisite service period pursuant to customer agreements to provide various customization and development services.

Goodwill

Goodwill is the excess of purchase price over the fair value of net assets acquired in business acquisitions. Goodwill is subject to, at a minimum, an annual impairment assessment of its carrying value. Additional impairment assessments would be performed if events and circumstances warranted such additional assessments during the year. Goodwill impairment is deemed to exist if the net book value of our reporting unit exceeds its estimated fair value. Estimated fair value of our reporting unit is determined utilizing the value implied by our year-end quoted stock price. We did not record any goodwill impairments during fiscal years 2015, 2014 or 2013.

We have one reporting unit which includes our product lines, the base technology which we obtained as part of our November 2002 acquisition of Unित्रact Syringe Pty Limited, and the manufacturing capability which we obtained in our January 2007 acquisition of Integrated BioSciences, Inc.

In estimating the reporting unit's fair value for purposes of our fiscal year 2015 impairment assessment, management compared the carrying value of our reporting unit to our market capitalization as of June 30, 2015, which is our annual impairment testing date. Our market capitalization of approximately \$283.7 million, based on the quoted stock price on NASDAQ, was in excess of our stockholders' deficit of \$17.9 million. Management also considered that market capitalization through early September 2015 continued to be in excess of the carrying value.

Research and Development Expense

Research and development expense consist primarily of payroll and related personnel expenses (including share-based compensation expense), fees paid to external service providers, costs of materials, components and supplies, costs for facilities, tooling and equipment and costs related to customization and development service arrangements and developing prototype products and samples used for various evaluation, testing and related activities for existing and potential customers.

Share-Based Compensation

We grant equity awards to our employees, directors, consultants and service providers. Certain employee and director awards vest over stated vesting periods and others also require achievement of specific performance or market conditions. We expense the grant-date fair value of awards to employees and directors over their respective vesting periods. To the extent that employee and director awards vest only upon the achievement of a specific performance condition, expense is recognized over the period from the date management determines that the performance condition is probable of achievement through the date they are expected to be met. Awards granted to consultants and service providers are sometimes granted for past services, in which case their fair value is expensed on their grant date, while other awards require future service, or the achievement of performance or market conditions. Timing of expense recognition for consultant awards is similar to that of employee and director awards; however, aggregate expense is re-measured each quarter-end based on the then fair value of the award through the vesting date of the award. We estimate the fair value of stock options using the Black-Scholes option-pricing model, with the exception of market-based grants, which are valued based on the Monte Carlo option pricing model. Option pricing methods require the input of highly subjective assumptions, including the expected stock price volatility.

Property, plant and equipment

We evaluate the recoverability of the recorded value of long-lived assets periodically to determine if facts and circumstances exist that would indicate that the assets might be impaired or that the useful lives should be modified. As part of this valuation, we develop projections of undiscounted future cash flows of the asset or the asset group. Our projections of undiscounted cash flows include a combination of revenue from customization and development activities, capital expenses that may be necessary to support projected product sales and commercial product sales. As customization and development activities are completed, commercial product sales are expected to scale-up. Expectations of future commercial product sales included in the projections used for our impairment analysis are based on customer-specific information as well as market estimates relating to the anticipated therapies being targeted for use with our products. These projections also include assumptions of future sales growth and profitability based on contracts entered into with customers as well as future contracts to be entered into based on the current discussions and negotiations with existing and prospective customers.

Sales projections are based on assumptions including a transition in the market toward patient self-administration of injectable therapies as well as transitions in the market toward biologic therapies in the pharmaceutical industry development pipeline. Our future sales could also be impacted by factors such as our ability to obtain new and retain existing customers, the timing and extent of the customers' product development activities as well as the regulatory approval process, drug efficacy and industry acceptance of injectable therapies. If our future sales or projections of future sales are impacted by any one or more of the preceding factors, we will reassess the recorded value of the long-lived assets. If impairment is indicated, an adjustment will be made to reduce the carrying amount of these assets to their fair value.

Fair value measurements

In accordance with Accounting Standards Codification ("ASC") 820, Fair Value Measurements and Disclosures, we measure fair value based on a hierarchy for inputs used in measuring fair value that maximizes

the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. The fair value hierarchy is broken down into three levels based on the source of inputs.

The carrying value of financial instruments such as accounts receivable, accounts payable and accrued expenses are reasonable estimates of their fair value because of the short maturity of these items. We believe that the current carrying amount of our long-term debt approximates fair value because the interest rates on these instruments are similar to those rates that we would currently be able to receive for similar instruments of comparable maturity.

We have elected to measure our royalty liability at fair value in accordance with ASC 825, Financial Instruments. The fair value of the royalty liability is based on significant inputs not observable in the market, which require it to be reported as a Level 3 liability within the fair value hierarchy. The valuation uses a methodology and assumptions that we believe would be made by a market participant. In particular, the valuation analysis uses a discounted cash flow methodology under the income approach based on the present value sum of payments to be made in the future. The fair value of the royalty liability is estimated by applying a risk adjusted discount rate to the adjusted royalty revenue stream. These fair value estimates are most sensitive to changes in the payment stream.

Interest expense

We recognize interest expense in the consolidated statements of operations and comprehensive loss for all debt instruments using the effective interest method. The effective interest method is a method of calculating the amortized cost of a financial liability and of allocating the interest expense over the relevant period. The effective interest rate is the rate that exactly discounts the estimated future cash payments through the expected life of the financial instrument to the net carrying amount of the financial liability. The application of the method has the effect of recognizing expense payable on the instrument evenly in proportion to the amount outstanding over the period to maturity or repayment. In calculating the effective interest rate, we estimate cash flows considering all contractual terms of the financial instrument, including fees for early redemption and all other premiums and discounts.

Recently Issued Accounting Pronouncements

See note 3 “Recently Issued Accounting Pronouncements” to our consolidated financial statements included in this Annual Report on Form 10-K.

Basis of Presentation

Revenue

We derive revenue primarily from industrialization and development programs with our customers. The agreements with our customers generally provide for fees to be paid to us for providing specific products or services. Certain of these agreements provide for fees to be paid upon completion of certain agreed-upon milestones. In instances where these milestones are substantive, we recognize revenue when these agreed-upon substantive milestones have been completed and there is no further performance obligation related to the substantive milestone. Certain of our agreements provide for fees to be paid for specific services to be rendered or the provision of certain deliverables, and we recognize revenue upon completion of the related service or deliverable. Certain of our agreements provide for fees to be paid on an ongoing basis over the life of the agreement for agreed-upon services, and we recognize revenue ratably over the requisite service period. We also recognize revenue on certain agreements under the proportional performance method.

Cost of product sales

We include the following expenses in cost of product sales: amounts paid for the cost of raw materials and component parts used to manufacture products for sales to customers as well as direct labor expenses and

manufacturing overhead expenses used in the commercial production process. Cost of product sales does not include any expense related to labor or overhead costs incurred on customization and development service arrangements, raw materials and components for these activities, or developing prototype products or samples used for various evaluation and related activities under customer agreements.

Operating expenses

Operating expenses primarily include costs related to research and development, selling, general and administrative expenses, as well as depreciation and amortization expense.

Research and development costs

Research and development costs consist primarily of payroll and related personnel expenses (including share-based compensation expense), fees paid to external service providers, costs of materials, components and supplies, costs for facilities, tooling and equipment and costs related to customization and development service arrangements and developing prototype products and samples used for various evaluation, testing and related activities for existing and potential customers.

Selling, general and administrative costs

Selling, general and administrative costs include marketing and commercial development costs, quality assurance and regulatory costs, accounting and financial related costs, information and technology costs, legal and professional fees, corporate facility costs, corporate payroll and related benefit costs (including share-based compensation expense).

Depreciation

Depreciation is calculated on a straight-line basis over the estimated useful lives of the related assets, which range from 40 years for our York, Pennsylvania facility to 2 to 15 years for machinery, equipment, furniture and software and the lesser of the lease term or estimated useful life for leasehold improvements. Intangible assets are being amortized using the straight-line method over their estimated useful lives of 15 years.

Interest expense

Interest expense includes the cash and non-cash interest cost for all debt instruments. Interest expense is recognized under the effective interest method such that non-cash interest includes the additional expense recognized over and above the cash interest paid during a period as a result of the application of the effective interest method.

Change in fair value of financial instruments

Change in fair value of financial instruments includes the change in the Amended Royalty Agreement (defined below) liability, which is marked to fair value on a quarterly basis.

Net loss

Net loss includes the results from revenue recognized during the period after deducting all operating and non-operating expenses.

Results of Operations

The following table summarizes our results of operations for fiscal years 2015, 2014 and 2013:

	Fiscal Years Ended June 30,		
	2015	2014	2013
	(in thousands, except per share data)		
Revenue	\$ 13,158	\$ 14,689	\$ 2,743
Cost of product sales	—	—	128
Research and development	52,487	34,111	21,749
Selling, general and administrative	36,176	27,894	32,437
Depreciation and amortization	4,923	4,079	9,487
Total operating expenses	93,586	66,084	63,801
Operating loss	(80,428)	(51,395)	(61,058)
Interest expense	6,368	7,332	2,392
Other income	(226)	(228)	(252)
Change in fair value of financial instruments	4,279	(600)	—
Net loss	<u>\$(90,849)</u>	<u>\$(57,899)</u>	<u>\$(63,198)</u>
Net loss per share:			
Basic and diluted net loss per share	<u>\$ (0.81)</u>	<u>\$ (0.59)</u>	<u>\$ (0.78)</u>

Fiscal Year 2015 Compared to Fiscal Year 2014

Revenue. Revenue decreased by \$1.5 million or 10.4% during fiscal year 2015 compared to fiscal year 2014 due to less revenue being recognized related to development activities for various customers. During fiscal year 2015, we recognized \$5.1 million in revenue related to substantive milestones that were completed during the year pursuant to customer agreements to provide customization and development services, clinical support services, collaborative research activities and testing support services. During fiscal year 2015, we recognized \$8.1 million in revenue related to services rendered on a time and materials basis, proportional performance method and/or straight-line basis over the requisite service period pursuant to customer agreements to provide various customization and development services. During fiscal year 2014, we recognized \$8.1 million in revenue related to substantive milestones that were completed during the year pursuant to customer agreements to provide customization and development services, clinical support services, collaborative research activities and testing support services. During fiscal year 2014, we recognized \$4.3 million in revenue related to services rendered on a time and materials basis pursuant to customer agreements to provide various customization and development services. Also, during fiscal year 2014, we recognized \$2.3 million of revenue related to our development agreement with Sanofi which was superseded by a supply agreement with Sanofi.

Research and development expenses. Research and development expenses increased in fiscal year 2015 by \$18.4 million or 53.9% compared to fiscal year 2014 primarily due to increased payroll and related costs of \$7.5 million and increased share-based compensation expense of \$0.7 million related to increased headcount to support ongoing and future customer programs, as well as increased material and tooling costs of \$8.5 million, and increased other costs of \$1.7 million related to customer programs. The increased investment in research and development during fiscal year 2015 related to the supply of products and components to existing customers including for customization, industrialization and development programs and prospective customers to support evaluation processes and user studies that are typically undertaken prior to the anticipated signing of contracts. We expect to continue our investment in research and development as we service existing customers and enter into additional customer agreements in future periods.

Selling, general and administrative expenses. Selling, general and administrative expenses increased in fiscal year 2015 by \$8.3 million or 29.7% compared to fiscal year 2014, primarily due to increased share-based compensation expense of \$2.8 million, increased legal and professional fees of \$2.3 million, increased payroll and related costs of \$2.2 million and increased other administrative costs of \$1.0 million.

Depreciation and amortization expense. Depreciation and amortization expense increased in fiscal year 2015 by \$0.8 million or 20.7% compared to fiscal year 2014, primarily as a result of machinery and equipment placed in service during the current year.

Interest expense. Interest expense decreased in fiscal year 2015 by \$1.0 million or 13.1% compared to fiscal year 2014, as a result of lower interest expense of \$4.7 million due to debt that was refinanced with a term loan with the Lender in the prior year and interest of \$2.2 million that was capitalized as part of construction in progress during the current year partially offset by higher interest during the current year of \$5.9 million related to the term loan with the Lender.

Change in fair value of financial instruments. Change in fair value of financial instruments increased by \$4.9 million in fiscal year 2015 compared to fiscal year 2014, primarily due to higher royalty rates as a result of the Amendment to the Royalty Agreement we entered into with the Lender on September 30, 2014.

Net loss and net loss per share. Net loss during fiscal years 2015 and 2014 was \$90.8 million and \$57.9 million, respectively. Basic and diluted net loss per share was \$0.81 and \$0.59 during fiscal years 2015 and 2014, respectively, on weighted average shares outstanding of 112,194,900 and 98,062,664 during fiscal years 2015 and 2014, respectively. The increase in the weighted average shares outstanding was primarily due to the issuance of common stock in connection with our February 2015 equity financing as well as shares issued under the Sales Agreement during fiscal year 2015.

Fiscal Year 2014 Compared to Fiscal Year 2013

Revenue. Revenue increased by \$11.9 million or 436.0% during fiscal year 2014 compared to fiscal year 2013 due to additional revenue recognized related to development activities for various customers. During fiscal year 2014, we recognized \$8.1 million in revenue related to substantive milestones that were completed during the year pursuant to customer agreements to provide customization and development services, clinical support services, collaborative research activities and testing support services. During fiscal year 2014, we recognized \$4.3 million in revenue related to services rendered on a time and materials basis pursuant to customer agreements to provide various customization and development services. Also, during fiscal year 2014, we recognized \$2.3 million of revenue related to our development agreement with Sanofi which was superseded by a supply agreement with Sanofi. Since these revenues are based in euros, fluctuation in the amount of revenue recognized will result from fluctuations in foreign currency translation rates. During fiscal year 2013, we recognized revenue from our former agreement with Sanofi in the amount of \$2.6 million and \$0.1 million from other sales.

Research and development expenses. Research and development expenses increased in fiscal year 2014 by \$12.4 million or 57.0% compared to fiscal year 2013 primarily due to increased payroll and related costs of \$5.1 million and increased share-based compensation expense of \$1.7 million related to increased headcount to support ongoing and future customer programs, as well as increased material and tooling costs of \$3.9 million, and increased third party contracting costs of \$1.7 million related to customer programs. The increased investment in research and development during fiscal year 2014 related to the supply of products and components to existing customers including for customization, industrialization and development programs and prospective customers to support evaluation processes and user studies that are typically undertaken prior to the anticipated signing of contracts.

Selling, general and administrative expenses. Selling, general and administrative expenses decreased in fiscal year 2014 by \$4.5 million or 14.0% compared to fiscal year 2013, primarily due to decreased share-based compensation expense of \$6.6 million, partially offset by increased legal and professional fees of \$0.9 million, increased payroll and related costs of \$0.5 million and increased other administrative costs of \$0.7 million.

Depreciation and amortization expense. Depreciation and amortization expense decreased in fiscal year 2014 by \$5.4 million or 57.0% compared to fiscal year 2013, primarily as a result of the disposal of equipment used to manufacture the discontinued Unitract product line during fiscal year 2013.

Interest expense. Interest expense increased in fiscal year 2014 by \$4.9 million or 207.0% compared to fiscal year 2013, as a result of \$1.2 million paid in connection with the term loan which we entered into during March 2014 and \$3.7 million related to our settlement agreement with Varilease Finance, Inc., or Varilease, entered into during fiscal year 2014.

Net loss and net loss per share. Net loss during fiscal years 2014 and 2013 was \$57.9 million and \$63.2 million, respectively. Basic and diluted net loss per share was \$0.59 and \$0.78 during fiscal years 2014 and 2013, respectively, on weighted average shares outstanding of 98,062,664 and 81,165,773 during fiscal years 2014 and 2013, respectively. The increase in the weighted average shares outstanding was primarily due to the issuance of common stock in connection with our February 2013 equity financing as well as shares issued under the Sales Agreement during fiscal year 2014.

Liquidity and Capital Resources

To date, we have funded our operations primarily from a combination of term loans, equity issuances, borrowings under our bank mortgages, and payments from various customers. We have incurred recurring losses from operations as well as negative cash flows from operating activities during fiscal years 2015, 2014 and 2013, and anticipate incurring additional losses and negative cash flow until such time that we can generate sufficient revenue from the sale, customization, or exclusive use and licensing of our injectable drug delivery systems to our customers. As of June 30, 2015, cash and cash equivalents were \$12.3 million, restricted cash was \$2.4 million and our long-term debt was \$80.4 million. As of June 30, 2014, cash and cash equivalents were \$8.4 million, restricted cash was \$2.4 million and our long-term debt was \$55.4 million. The restricted cash relates to amounts that must remain in cash deposits under our loan agreement with Metro Bank.

During July 2015, we entered into the Sales Agreement with Cantor, pursuant to which we may, from time to time, issue and sell shares of common stock, having an aggregate offering price of up to \$25.0 million. Through September 14, 2015, we have issued 2,870,689 shares for net proceeds of \$3.8 million under the Sales Agreement.

During July 2015, we entered the Purchase Agreement with LPC, pursuant to which we have the right to sell, from time to time, to LPC up to \$45.0 million in shares of the Company's common stock, subject to certain limitations and conditions set forth in the Purchase Agreement. Through September 14, 2015, we issued 3,244,650 shares of common stock to LPC and received net proceeds of approximately \$4.8 million after expenses.

In February 2015, we issued 12,650,000 shares of common stock and raised \$44.7 million, net of issuance costs, through an underwritten registered public offering.

On March 12, 2014, we entered into a credit agreement with the Lender. Under the terms of the credit agreement, the Lender agreed to provide term loans to us in the aggregate principal amount of up to \$60.0 million. A first tranche loan of \$40.0 million was drawn on the Closing Date and a further two tranches each of \$10.0 million were committed by the Lender and were to be funded on each of December 15, 2014 and June 15, 2015, subject to and in accordance with the terms of the credit agreement. On September 30, 2014 we entered into a First Amendment to the Credit Agreement pursuant to which we received the proceeds from the first \$10.0 million tranche on October 1, 2014 and the proceeds from the second \$10.0 million tranche on November 10, 2014. Under the Amended Credit Agreement, Borrower's prepayments and repayments of any unpaid principal amount of the Loans shall include a 10.0% repayment premium (with certain enumerated exceptions). The Amended Credit Agreement contains customary representations and warranties in favor of the Lender. The Amended Credit Agreement also contains certain covenants relating to financial performance, liquidity targets and the retention of certain members of management. As of and for

the year ended June 30, 2015, the Company is in compliance with all the loan covenants set forth in the Amended Credit Agreement. However, there can be no assurance that the Company will be able to maintain the minimum liquidity target or achieve the minimum cash revenue covenants during the 12-month period from June 30, 2015.

Borrower can make voluntary repayments at any time of any unpaid principal amount of the loans, plus a 10.0% repayment premium. Borrower must make mandatory prepayments in certain prescribed circumstances, including, without limitation, certain dispositions of assets and certain casualty events. In such events, Borrower must prepay to Lender 100% of the net cash proceeds received.

The Amended Credit Agreement is secured by the assets of the Company and its subsidiaries. The Company, Cross Farm, Unilife Medical Solutions Limited, or UMSL, and Unitract Syringe have guaranteed the performance by Borrower of its obligations under the Amended Credit Agreement. The security interests granted by Borrower, the Company, Cross Farm, UMSL and Unitract Syringe are evidenced by, among other things, a Pledge and Security Agreement, dated March 12, 2014, by Borrower, the Company, Cross Farm LLC, UMSL and Unitract Syringe in favor of Lender, for itself and as agent for ROS, an Open-End Commercial Mortgage and Security Agreement, dated March 12, 2014, by and between Cross Farm and Lender, for itself and as agent for ROS, and a General Security Deed, dated March 12, 2014, by Unitract Syringe, UMSL and the Company in favor of the Lender, for itself and as agent for ROS.

The Amended Credit Agreement contains customary representations and warranties in favor of the Lender. The Amended Credit Agreement also contains certain covenants, including among other things, covenants relating to financial performance, liquidity targets and the retention of certain members of management.

In the event of default, Borrower must prepay to Lender any unpaid principal amount of the loans drawn down, together with all accrued and unpaid interest thereon plus a 10.0% repayment premium. An event of default could also result in the Lender enforcing its security over the assets of Borrower, the Company, Cross Farm, UMSL and Unitract Syringe in accordance with the terms of the Amended Credit Agreement and the related security agreements.

Concurrent with the First Amendment to the Credit Agreement, we entered into the First Amendment to the Royalty Agreement, or the Amended Royalty Agreement. Pursuant to and subject to the terms of the Amended Royalty Agreement, Borrower has agreed to pay the Lender 3.875% on the first \$50.0 million of net sales in each fiscal year, plus 1.500% of net sales in excess of \$50.0 million and up to and including \$100.0 million in each fiscal year, plus 0.375% of net sales in excess of \$100.0 million in each fiscal year. Borrower has the right to buyout the Amended Royalty Agreement at any time on or before March 12, 2018 at a reduced amount. The buy-out amount ranges from \$9.75 million to \$26.25 million (such amount to be determined based on when the buy-out option is exercised), less amounts previously paid by Borrower to Lender pursuant to the Amended Royalty Agreement.

During October 2012, we entered into a sales agreement, pursuant to which we issued and sold shares of common stock, from time to time, having an aggregate offering price of up to \$45.0 million. During the year ended June 30, 2015, we issued 5,808,800 shares of common stock and raised approximately \$12.4 million under the old sales agreement, which was the full remaining amount available for sale under the old sales agreement. As a result, we have completed use of the full facility available under the old sales agreement.

We are in the process of investing in our facilities in anticipation of meeting customer demand. Specifically, we are reconfiguring our existing cleanrooms and also installing additional clean room manufacturing space within the existing footprint at our York production facility to accommodate additional assembly lines and related activities for our Unifill products and wearable injectors that will support planned customer demand during fiscal year 2016 and beyond. Accordingly, we have secured pre-approval from York County, Pennsylvania to construct an additional 100,000 square foot of production space at our York facility at a future date. As we take receipt of additional assembly lines where we have made large up-front payments, we may secure capital equipment financing, where appropriate, to support the continued scale-up of our production capabilities.

We have incurred recurring losses from operations as well as negative cash flows from operating activities in each of the years in the three-year period ended June 30, 2015 and anticipate incurring additional losses and negative cash flows until such time that we can generate sufficient revenue from the sale, customization, or exclusive use and licensing of our proprietary range of injectable drug delivery systems to pharmaceutical and biotechnology customers. These factors raise substantial doubt about our ability to continue as a going concern. In order for us to continue operations beyond the next 12 months and be able to discharge our liabilities and commitments in the normal course of business, we have taken or will take the following steps delineated below, not all of which are entirely within our control, to address our cash requirements.

On September 2, 2015, we announced that we have engaged Morgan Stanley & Co. LLC to conduct a review of strategic alternatives to maximize shareholder value in response to third party initiated expressions of interest. Potential strategic alternatives to be explored and evaluated during the review process may include a possible sale of our Company, a strategic partnership with one or more parties or the licensing of some of our proprietary technologies. We cannot provide any commitment regarding when or if this strategic review process will result in any type of transaction and no assurance can be given that we will determine to pursue a potential sale, strategic partnership or licensing arrangement.

We continue to have discussions with current and prospective customers for many active programs in our commercial pipeline and have executed several agreements featuring a combination of revenue streams including exclusivity fees, device customization programs and supply contracts that have begun to generate cash payments to us during fiscal year 2015. We expect to continue to execute agreements and generate additional cash payments during fiscal year 2016. Given the substantial size, complexity and long-term duration of many of these prospective agreements, some can take a significant time to negotiate and finalize.

Our near-term capital needs depend on many factors, including our ability to manage our costs, the amount and timing of revenue received from customer contracts, and our ability to successfully utilize the above equity facilities. We continue to evaluate other financing alternatives to provide additional operating funds on terms that are consistent with our business plans. In addition we have conducted a review of our operations and implemented a plan to reduce operating expenses and delay capital expenditures to align with current business conditions. As part of the evaluation, on September 9, 2015, our Board of Directors approved a reduction of approximately 17% of our workforce. The workforce reduction is expected to reduce operating costs by approximately \$4.3 million. In connection with this initiative, we expect to incur a charge of approximately \$0.4 million to operating expenses in the three month period ending September 30, 2015. We plan to closely monitor expenses and attempt to further reduce, if necessary, the amount of cash used in operating activities and capital spending by scaling back or delaying capital expenditures, delaying investment in further research and development, or further workforce reductions.

We estimate that our cash and cash equivalents as of June 30, 2015, along with our restricted cash, together with the additional proceeds raised and that may be raised from the Purchase Agreement and New Sales Agreement, and combined with anticipated cash to be generated from existing and prospective customer agreements are expected to provide us with sufficient liquidity for 12 months from the date the consolidated financial statements are issued. However, there can be no assurance that such cash from customer agreements or proceeds from the Purchase Agreement and New Sales Agreement will be available when needed, as such sources of liquidity are not entirely within our control. If we are unable to obtain adequate financing or engage in a strategic transaction on acceptable terms and when needed, we will be required to implement further cost reduction strategies. In addition, a breach of any of the covenants related to our debt instruments could result in a default under the applicable agreements which could result in a higher rate of interest to be paid or the lenders could elect to declare all amounts outstanding under the applicable agreements to be immediately due and payable. If the lenders were to make such a demand for repayment, we would be unable to pay the obligations as we do not have existing facilities or sufficient cash on hand to satisfy these obligations and would need to seek alternative financing. These factors, and the factors described above, continue to raise substantial doubt about our ability to continue as a going concern. The accompanying consolidated financial statements have been prepared

on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

The following table summarizes our cash flows during the fiscal years 2015, 2014 and 2013:

	Fiscal Years Ended June 30,		
	2015	2014	2013
	(In thousands)		
Net cash provided by (used in):			
Operating activities	\$(55,201)	\$(36,601)	\$(41,333)
Investing activities	(16,633)	(12,149)	(2,240)
Financing activities	75,750	51,287	37,909

Fiscal Year 2015 Compared to Fiscal Year 2014

Net Cash Used in Operating Activities

Net cash used in operating activities during fiscal year 2015 was \$55.2 million compared to \$36.6 million during fiscal year 2014. The increase in net cash used in operating activities was primarily due to increased research and development costs of \$17.7 million (exclusive of noncash expenses), and net other items \$0.9 million.

Net Cash Used in Investing Activities

Net cash used in investing activities during fiscal year 2015 and fiscal year 2014 was \$16.6 million and \$12.1 million, respectively. This increase was primarily as a result of costs incurred in connection with the purchase of machinery and related equipment, facility expansion and cleanroom reconfiguration.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during fiscal year 2015 was \$75.8 million compared to \$51.3 million during fiscal year 2014. During fiscal year 2015, we received \$44.7 million in net proceeds from our public offering of common stock in February 2015, \$20.0 million in aggregate proceeds from the two additional tranches under the Amended Credit Agreement with the Lender and \$12.4 million of proceeds in connection with our public offering of common stock under the old sales agreement which was partially offset by \$0.6 million in principal debt repayments and \$0.7 million in royalty liability payments. During fiscal year 2014, we received \$40.0 million from our March 2014 term loan, \$16.9 million in connection with our public offering of common stock under the old sales agreement and \$2.5 million upon the exercise of stock options. These amounts were partially offset by principal debt payments and financing costs of \$8.1 million.

Fiscal Year 2014 Compared to Fiscal Year 2013

Net Cash Used in Operating Activities

Net cash used in operating activities during fiscal year 2014 was \$36.6 million compared to \$41.3 million during fiscal year 2013. The decrease in net cash used in operating activities was primarily due to cash receipts from customers of \$23.7 million partially offset by increased research and development costs of \$10.7 million, selling, general and administrative expenses of \$2.2 million and interest expense of \$4.9 million (exclusive of noncash expenses).

Net Cash Used in Investing Activities

Net cash used in investing activities during fiscal year 2014 and fiscal year 2013 was \$12.1 million and \$2.2 million, respectively. This increase was primarily as a result of costs incurred in connection with the purchase of machinery and related equipment, facility expansion and cleanroom reconfiguration.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during fiscal year 2014 was \$51.3 million compared to \$37.9 million during fiscal year 2013. During fiscal year 2014, we received \$40.0 million from our March 2014 term loan, \$16.9 million in connection with our public offering of common stock under the Sales Agreement and \$2.5 million upon the exercise of stock options. These amounts were partially offset by principal debt payments and financing costs of \$8.1 million. During fiscal year 2013, we received \$42.7 million in connection with the issuance of common stock and warrants, partially offset by principal debt repayments of \$5.0 million.

Contractual Obligations and Commitments

The following table provides information regarding our contractual obligations as of June 30, 2015:

	Payments Due by Period				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
			(In thousands)		
Long-term debt and related interest	\$118,827	\$ 7,815	\$15,120	\$79,234	\$16,658
Operating leases	8,918	1,237	2,500	2,542	2,639
Purchase obligations	17,620	17,620	—	—	—
Total contractual obligations	<u>\$145,365</u>	<u>\$26,672</u>	<u>\$17,620</u>	<u>\$81,776</u>	<u>\$19,297</u>

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as such term is defined in the SEC rules.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk from changes in interest rates and foreign currency exchange rates. Changes in these factors could cause fluctuations in our results of operations and cash flows.

Interest Rate Risk

We face exposure to changes in interest rates primarily relating to our variable rate long-term debt pursuant to the OrbiMed Amended Credit Agreement. As of June 30, 2015, we had \$60.0 million outstanding under the Amended Credit Agreement. The loans bear interest at 9.25% per annum plus LIBOR or 1.0% (whichever is greater), payable in cash quarterly, and as otherwise described in the Amended Credit Agreement. On June 30, 2015, the three-month LIBOR rate was 0.28%. Accordingly, we used a 10.25% interest rate. As of June 30, 2015, a ten basis point adverse change in LIBOR would not impact our total monthly interest expense related to the OrbiMed Credit Agreement as our interest expense would not be tied to LIBOR unless or until LIBOR was greater than 1.0%.

We also face exposure to interest rate risk relating to our cash and cash equivalents that are invested in money market funds with highly liquid short term investments. We currently do not utilize derivative instruments to mitigate changes in interest rates.

As of June 30, 2015, a ten basis point adverse change in interest rates relating to our cash and cash equivalents that are invested in money market funds with highly liquid short term investments would have decreased our aggregate reported cash and cash equivalents by less than 1.0%.

Foreign Currency Exchange Rate Fluctuations

Certain of our revenues are derived from payments under our exclusive agreements received in euros while we incur most of our expenses in U.S. dollars and Australian dollars. In addition, a portion of our cash and cash

equivalents and investments are held at Australian banking institutions and are denominated in Australian dollars. We are exposed to foreign currency exchange rate risks on these amounts. We currently do not utilize options or forward contracts to mitigate changes in foreign currency exchange rates. For U.S. reporting purposes, we translate all assets and liabilities of our non-U.S. entities into U.S. dollars using the exchange rate as of the end of the related period and we translate all revenues and expenses of our non-U.S. entities using the average exchange rate during the applicable period.

As of June 30, 2015, a ten percent adverse change in foreign exchange rates versus the U.S. dollar would have decreased our aggregate reported cash and cash equivalents by less than 1.0%.

Item 8. Financial Statements and Supplementary Data

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	<u>Page</u>
Management's Report on Internal Control Over Financial Reporting	56
Reports of Independent Registered Public Accounting Firm	57
Consolidated Balance Sheets as of June 30, 2015 and 2014	59
Consolidated Statements of Operations and Comprehensive Loss for the years ended June 30, 2015, 2014 and 2013	60
Consolidated Statements of Stockholders' (Deficit) Equity for the years ended June 30, 2015, 2014 and 2013	61
Consolidated Statements of Cash Flows for the years ended June 30, 2015, 2014 and 2013	62
Notes to Consolidated Financial Statements	63

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Our internal control over financial reporting was designed to provide reasonable assurance to management and our Board of Directors regarding the reliability of financial reporting and the fair presentation of our consolidated financial statements.

With the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control-Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on our evaluation, our management concluded that our internal control over financial reporting was effective as of June 30, 2015 to provide reasonable assurance regarding the reliability of financial reporting and the fair presentation of our consolidated financial statements.

KPMG LLP, an independent registered public accounting firm, audited our internal control over financial reporting as of June 30, 2015. Their audit report can be found on page 57.

/s/ Alan Shortall

Alan Shortall
Chairman and Chief Executive Officer

/s/ David C. Hastings

David C. Hastings
Chief Financial Officer

/s/ Dennis P. Pyers

Dennis P. Pyers
Controller and Chief Accounting Officer

September 14, 2015

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Unilife Corporation:

We have audited Unilife Corporation and subsidiaries (the Company) internal control over financial reporting as of June 30, 2015, based on criteria established in *Internal Control-Integrated Framework* (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of June 30, 2015, based on criteria established in *Internal Control-Integrated Framework* (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Unilife Corporation and subsidiaries as of June 30, 2015 and 2014, and the related consolidated statements of operations and comprehensive loss, stockholders' (deficit) equity, and cash flows for each of the years in the three-year period ended June 30, 2015, and our report dated September 14, 2015 expressed an unqualified opinion on those consolidated financial statements. Our report on the consolidated financial statements dated September 14, 2015 contains an explanatory paragraph that states there is substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

Harrisburg, Pennsylvania
September 14, 2015

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Unilife Corporation:

We have audited the accompanying consolidated balance sheets of Unilife Corporation and subsidiaries (the Company) as of June 30, 2015 and 2014, and the related consolidated statements of operations and comprehensive loss, stockholders' (deficit) equity, and cash flows for each of the years in the three-year period ended June 30, 2015. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Unilife Corporation and subsidiaries as of June 30, 2015 and 2014, and the results of their operations and their cash flows for each of the years in the three-year period ended June 30, 2015, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in note 2 to the consolidated financial statements, the Company has incurred recurring losses from operations and has limited cash resources, which raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of June 30, 2015, based on criteria established in *Internal Control-Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated September 14, 2015 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP

Harrisburg, Pennsylvania
September 14, 2015

UNILIFE CORPORATION AND SUBSIDIARIES

Consolidated Balance Sheets

	June 30,	
	2015	2014
	(In thousands, except share data)	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 12,303	\$ 8,368
Restricted cash	2,400	2,400
Accounts receivable	1,530	1,860
Inventories	151	142
Prepaid expenses and other current assets	656	1,108
Total current assets	17,040	13,878
Property, plant and equipment, net	66,148	54,588
Goodwill	9,685	11,830
Other assets	1,256	1,472
Total assets	<u>\$ 94,129</u>	<u>\$ 81,768</u>
Liabilities and Stockholders' (Deficit) Equity		
Current Liabilities:		
Accounts payable	\$ 4,042	\$ 3,583
Accrued expenses	5,074	3,339
Current portion of long-term debt	775	613
Deferred revenue	4,942	717
Total current liabilities	14,833	8,252
Long-term debt, less current portion	79,660	54,835
Deferred revenue	17,550	12,550
Total liabilities	<u>112,043</u>	<u>75,637</u>
Commitments and Contingencies (Note 8)		
Stockholders' (Deficit) Equity:		
Preferred stock, \$0.01 par value, 50,000,000 shares authorized as of June 30, 2015; none issued or outstanding as of June 30, 2015 and 2014	—	—
Common stock, \$0.01 par value, 250,000,000 shares authorized as of June 30, 2015; 131,976,153 and 103,617,278 shares issued, and 131,947,483 and 103,588,608 shares outstanding as of June 30, 2015 and 2014, respectively	1,320	1,036
Additional paid-in-capital	364,817	296,169
Accumulated deficit	(384,580)	(293,731)
Accumulated other comprehensive income	669	2,797
Treasury stock, at cost, 28,670 shares as of June 30, 2015 and 2014	(140)	(140)
Total stockholders' (deficit) equity	<u>(17,914)</u>	<u>6,131</u>
Total liabilities and stockholders' (deficit) equity	<u>\$ 94,129</u>	<u>\$ 81,768</u>

See accompanying notes to the consolidated financial statements.

UNILIFE CORPORATION AND SUBSIDIARIES
Consolidated Statements of Operations and Comprehensive Loss

	Year Ended June 30,		
	2015	2014	2013
	(In thousands, except per share data)		
Revenue	\$ 13,158	\$ 14,689	\$ 2,743
Cost of product sales	—	—	128
Research and development	52,487	34,111	21,749
Selling, general and administrative	36,176	27,894	32,437
Depreciation and amortization	4,923	4,079	9,487
Total operating expenses	<u>93,586</u>	<u>66,084</u>	<u>63,801</u>
Operating loss	(80,428)	(51,395)	(61,058)
Interest expense	6,368	7,332	2,392
Other income	(226)	(228)	(252)
Change in fair value of financial instruments	<u>4,279</u>	<u>(600)</u>	<u>—</u>
Net loss	(90,849)	(57,899)	(63,198)
Other comprehensive loss (income):			
Foreign currency translation	<u>2,128</u>	<u>(340)</u>	<u>978</u>
Comprehensive loss	<u><u>\$(92,977)</u></u>	<u><u>\$(57,559)</u></u>	<u><u>\$(64,176)</u></u>
Net loss per share:			
Basic and diluted net loss per share	<u><u>\$ (0.81)</u></u>	<u><u>\$ (0.59)</u></u>	<u><u>\$ (0.78)</u></u>

See accompanying notes to the consolidated financial statements.

UNILIFE CORPORATION AND SUBSIDIARIES
Consolidated Statements of Stockholders' (Deficit) Equity

	Common Stock		Additional	Accumulated	Accumulated	Treasury	Total
	Shares	Amount	Paid-In	Deficit	Other	Stock	
			Capital		Comprehensive		
					Income		
(In thousands, except share data)							
Balance as of June 30, 2012 . . .	75,849,439	\$ 758	\$212,326	\$(172,634)	\$ 3,435	\$(140)	\$ 43,745
Net loss	—	—	—	(63,198)	—	—	(63,198)
Foreign currency translation . . .	—	—	—	—	(978)	—	(978)
Share-based compensation							
expense	2,611,167	27	13,260	—	—	—	13,287
Issuance of common stock from							
public offering, net of							
issuance costs	15,605,400	156	39,526	—	—	—	39,682
Exercise of warrant to purchase							
common stock	1,424,220	14	2,820	—	—	—	2,834
Issuance of common stock upon							
exercise of stock options	112,332	1	225	—	—	—	226
Balance as of June 30, 2013 . . .	95,602,558	956	268,157	(235,832)	2,457	(140)	35,598
Net loss	—	—	—	(57,899)	—	—	(57,899)
Foreign currency translation . . .	—	—	—	—	340	—	340
Share-based compensation							
expense	1,593,096	16	8,300	—	—	—	8,316
Issuance of common stock from							
public offerings, net of							
issuance costs	5,012,153	50	16,806	—	—	—	16,856
Issuance of common stock upon							
exercise of stock options	1,409,471	14	2,906	—	—	—	2,920
Balance as of June 30, 2014 . . .	103,617,278	1,036	296,169	(293,731)	2,797	(140)	6,131
Net loss	—	—	—	(90,849)	—	—	(90,849)
Foreign currency translation . . .	—	—	—	—	(2,128)	—	(2,128)
Share-based compensation							
expense	9,890,075	99	11,676	—	—	—	11,775
Issuance of common stock from							
public offerings, net of							
issuance costs	18,458,800	185	56,949	—	—	—	57,134
Issuance of common stock upon							
exercise of stock options	10,000	—	23	—	—	—	23
Balance as of June 30, 2015 . . .	131,976,153	\$1,320	\$364,817	\$(384,580)	\$ 669	\$(140)	\$(17,914)

See accompanying notes to the consolidated financial statements.

UNILIFE CORPORATION AND SUBSIDIARIES

Consolidated Statements of Cash Flows

	Year Ended June 30,		
	2015	2014	2013
	(In thousands)		
Cash flows from operating activities:			
Net loss	\$(90,849)	\$(57,899)	\$(63,198)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	4,923	4,079	5,435
Loss on disposal of equipment	—	—	4,052
Share-based compensation expense	11,775	8,316	13,287
Recognition of deferred revenue	(125)	(3,187)	(2,623)
Non-cash interest expense	1,896	457	—
Change in fair value of financial instruments	4,279	(600)	—
Changes in assets and liabilities:			
Accounts receivable	330	(266)	388
Inventories	(9)	(71)	141
Prepaid expenses and other current assets	452	(704)	267
Other assets	87	(427)	(227)
Accounts payable	431	1,062	65
Accrued expenses	2,259	139	355
Deferred revenue	9,350	12,500	725
Net cash used in operating activities	(55,201)	(36,601)	(41,333)
Cash flows from investing activities:			
Purchases of property, plant and equipment	(16,633)	(12,149)	(2,240)
Net cash used in investing activities	(16,633)	(12,149)	(2,240)
Cash flows from financing activities:			
Proceeds from the issuance of long-term debt	20,000	40,000	—
Principal payments on long-term debt and capital lease agreements	(606)	(7,616)	(5,024)
Proceeds from the issuance of common stock, net of issuance costs	57,134	16,856	42,707
Proceeds from the exercise of options to purchase common stock	23	2,534	226
Payment of royalty liability	(749)	—	—
Payments of financing costs	(52)	(487)	—
Net cash provided by financing activities	75,750	51,287	37,909
Effect of exchange rate changes on cash	19	95	(10)
Net increase (decrease) in cash and cash equivalents	3,935	2,632	(5,674)
Cash and cash equivalents at beginning of year	8,368	5,736	11,410
Cash and cash equivalents at end of year	<u>\$ 12,303</u>	<u>\$ 8,368</u>	<u>\$ 5,736</u>
Supplemental disclosure of cash flow information			
Cash paid for interest	<u>\$ 6,467</u>	<u>\$ 3,222</u>	<u>\$ 2,479</u>
Supplemental disclosure of non-cash activities			
Purchases of property, plant and equipment in accounts payable and accrued expenses	<u>\$ 497</u>	<u>\$ 991</u>	<u>\$ 744</u>
Purchases of property, plant and equipment pursuant to capital lease agreements	<u>\$ —</u>	<u>\$ 125</u>	<u>\$ 74</u>

See accompanying notes to the consolidated financial statements.

UNILIFE CORPORATION AND SUBSIDIARIES

Notes to Consolidated Financial Statements

1. Description of Business

Unilife Corporation and subsidiaries (the “Company”) is a U.S. based designer, manufacturer and supplier of innovative injectable drug delivery systems that can enhance and differentiate the injectable drugs, biologics and vaccines, or collectively injectable therapies, of its pharmaceutical and biotechnology customers. The Company has a broad portfolio of proprietary product platforms, including pre-filled syringes, wearable injectors, insulin delivery systems, disposable and reusable auto-injectors, drug reconstitution delivery systems, ocular delivery systems and other systems for the targeted delivery of injectable therapies. Products within each platform are differentiated from competitors’ products with a series of innovative features designed to optimize the safe, simple and convenient administration of an injectable therapy. The Company sells its products directly to pharmaceutical and biotechnology companies who incorporate them into the drug-device combination product that is supplied pre-filled and ready for administration by end-users such as health-care providers or patients. Products within each of the Company’s platforms can be customized to address specific customer, therapy, patient and/or commercial requirements.

The Company’s growing base of customers include Sanofi, MedImmune, AbbVie, Novartis and Hikma. In addition to the filling, assembly and/or packaging of its product with an injectable therapy, the Company’s customers are also responsible for the regulatory approval, sale and marketing of their final drug-device combination product. With certain of our devices that we could sell directly to healthcare providers or end users without having them pre-filled with a drug by a pharmaceutical company, we would be responsible for the regulatory approval, sale and marketing of the final device. In addition to product sales, the Company can generate revenue and cash receipts from customization programs, upfront fees and exclusivity or royalty payments.

The Company is a Pennsylvania based and Delaware incorporated business since 2009, and was originally established in Australia in 2002.

2. Liquidity

The Company has incurred recurring losses from operations as well as negative cash flows from operating activities in each of the years in the three-year period ended June 30, 2015 and anticipates incurring additional losses and negative cash flows until such time that it can generate sufficient revenue from the sale, customization, or exclusive use and licensing of its proprietary range of injectable drug delivery systems to pharmaceutical and biotechnology customers. These factors raise substantial doubt about the Company’s ability to continue as a going concern. In order for the Company to continue operations beyond the next 12 months and be able to discharge its liabilities and commitments in the normal course of business, the Company has taken or will take the following steps delineated below, not all of which are entirely within the Company’s control, to address its cash requirements.

On July 29, 2015, the Company entered into a Controlled Equity Offering Sales Agreement (the “New Sales Agreement”) with Cantor Fitzgerald & Co., pursuant to which the Company may, from time to time, issue and sell shares of common stock, having an aggregate offering price of up to \$25.0 million. Through September 14, 2015, the Company has issued 2,870,689 shares for net proceeds of \$3.8 million under the New Sales Agreement.

On July 29, 2015, the Company entered into an equity purchase agreement (the “Purchase Agreement”) with Lincoln Park Capital Fund, LLC (“LPC”), pursuant to which the Company may sell, from time to time, to LPC up to \$45.0 million in shares of the Company’s common stock through July 2017, subject to certain limitations and conditions set forth in the Purchase Agreement. Through September 14, 2015, the Company issued 3,244,650 shares of common stock to LPC and received net proceeds of approximately \$4.8 million after expenses.

On September 2, 2015, the Company announced that it has engaged Morgan Stanley & Co. LLC to conduct a review of strategic alternatives to maximize shareholder value in response to third party initiated expressions of interest. Potential strategic alternatives to be explored and evaluated during the review process may include a possible sale of the Company, a strategic partnership with one or more parties or the licensing of some of the Company's proprietary technologies. The Company cannot provide any commitment regarding when or if this strategic review process will result in any type of transaction and no assurance can be given that the Company will determine to pursue a potential sale, strategic partnership or licensing arrangement.

The Company continues to have discussions with current and prospective customers for many active programs in its commercial pipeline and has executed several agreements featuring a combination of revenue streams including exclusivity fees, device customization programs and supply contracts that have begun to generate cash payments to the Company during fiscal year 2015. The Company expects to continue to execute agreements and generate additional cash payments during fiscal year 2016. Given the substantial size, complexity and long-term duration of many of these prospective agreements, some can take a significant time to negotiate and finalize.

The Company's near-term capital needs depend on many factors, including its ability to manage its costs, the amount and timing of revenue received from customer contracts, and its ability to successfully utilize the above equity facilities. The Company continues to evaluate other financing alternatives to provide additional operating funds on terms that are consistent with the Company's business plans. In addition the Company has conducted a review of its operations and implemented a plan to reduce operating expenses and delay capital expenditures to align with current business conditions. As part of the evaluation, on September 9, 2015, the Company's Board of Directors approved a reduction of approximately 17% of its workforce. The workforce reduction is expected to reduce operating costs by approximately \$4.3 million. In connection with this initiative, the Company expects to incur a charge of approximately \$0.4 million to operating expenses in the three month period ending September 30, 2015. The Company plans to closely monitor expenses and attempt to further reduce, if necessary, the amount of cash used in operating activities and capital spending by scaling back or delaying capital expenditures, delaying investment in further research and development, or further workforce reductions.

The Company estimates that its cash and cash equivalents as of June 30, 2015, along with its restricted cash, together with the additional proceeds raised and that may be raised from the Purchase Agreement and New Sales Agreement, and combined with anticipated cash to be generated from existing and prospective customer agreements are expected to provide the Company with sufficient liquidity for 12 months from the date the consolidated financial statements are issued. However, there can be no assurance that such cash from customer agreements or proceeds from the Purchase Agreement and New Sales Agreement will be available when needed, as such sources of liquidity are not entirely within the Company's control. If the Company is unable to obtain adequate financing or engage in a strategic transaction on acceptable terms and when needed, it will be required to implement further cost reduction strategies. In addition, a breach of any of the covenants related to the Company's debt instruments could result in a default under the applicable agreements which could result in a higher rate of interest to be paid or the lenders could elect to declare all amounts outstanding under the applicable agreements to be immediately due and payable. If the lenders were to make such a demand for repayment, the Company would be unable to pay the obligations as it does not have existing facilities or sufficient cash on hand to satisfy these obligations and would need to seek alternative financing. These factors, and the factors described above, continue to raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

3. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Unilife Corporation and its wholly-owned subsidiaries. The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”). All significant intercompany accounts and transactions have been eliminated in consolidation.

On January 27, 2010, Unilife became the parent company of UMSL upon completion of the redomiciliation under Australian law and UMSL’s stockholders and option holders exchanged their interests in UMSL for equivalent interests in Unilife.

References to the “Company” include Unilife Corporation and its consolidated subsidiaries, including UMSL, unless the context otherwise requires. References to “Unilife” are references solely to Unilife Corporation.

References to A\$ mean the lawful currency of the Commonwealth of Australia. References to € or euros are to the lawful currency of the European Union.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The estimates are principally in the areas of revenue recognition, royalty liability valuation and share-based compensation expense. Management bases its estimates on historical experience and various assumptions that are believed to be reasonable under the circumstances. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents consist primarily of cash on hand, deposits at banks and other short-term highly liquid investments with original maturities of three months or less. Cash equivalents are stated at cost, which approximates fair value.

Accounts Receivable

Accounts receivable are stated at amounts due from customers, which also represents the net realizable amount. The Company evaluates the collectability of its accounts receivable on a periodic basis and has historically not recorded an allowance for doubtful accounts. In instances in which management becomes aware of circumstances that may impair a particular customer’s ability to meet its obligation, the related receivable would be written off.

Inventories

Inventories consist primarily of raw materials. Inventories are stated at the lower of cost or market, with cost determined using the first in, first out method. The Company routinely reviews its inventory for obsolete, slow moving or otherwise impaired inventory and records estimated impairments in the periods in which they occur.

Property, Plant and Equipment

Property, plant and equipment, including significant improvements, are recorded at cost, net of accumulated depreciation and amortization. Repairs and maintenance are expensed as incurred.

Depreciation and amortization expense is recorded on a straight-line method over the estimated useful life of the asset as listed below:

<u>Asset Category</u>	<u>Useful Lives</u>
Building	40 years
Machinery and equipment	2 to 15 years
Computer software	3 to 7 years
Furniture and fixtures	3 to 7 years
Leasehold improvements	Shorter of leasehold improvement life or remaining term of lease

Interest cost incurred in connection with the development and construction of significant new machinery and equipment, as well as facility related costs have been capitalized as one of the elements of cost and are being amortized over the asset's respective useful life. Interest capitalized during the year ended June 30, 2015 was \$2.2 million. There was no capitalized interest during the years ended June 30, 2014 or 2013.

The Company evaluates the recoverability of the recorded value of long-lived assets periodically to determine if facts and circumstances exist that would indicate that the assets might be impaired or that the useful lives should be modified. As part of this valuation, the Company develops projections of undiscounted future cash flows of the asset or asset group. The projections of undiscounted cash flows include a combination of revenue from customization and development activities, capital expenses that may be necessary to support projected product sales and commercial product sales. As customization and development activities are completed, commercial product sales are expected to scale-up. Expectations of future commercial product sales included in the projections used for the impairment analysis are based on customer-specific information as well as market estimates relating to the anticipated drugs and therapies being targeted for use with the Company's products. These projections also include assumptions of future sales growth and profitability based on contracts entered into with customers as well as future contracts to be entered into based on the current discussions and negotiations with existing and prospective customers.

Sales projections are based on assumptions including a transition in the market toward patient self-administration of injectable therapies as well as transitions in the market toward biological-based drugs in the pharmaceutical industry development pipeline. The Company's future sales could also be impacted by factors such as its ability to obtain new and retain existing customers, the timing and extent of the customers' drug development activities as well as the regulatory approval process, drug efficacy and industry acceptance of injectable therapies. If the Company's future sales or its projections of future sales are impacted by any one or more of the preceding factors, it will reassess the recorded value of the long-lived assets. If impairment is indicated, an adjustment will be made to reduce the carrying amount of these assets to their fair value.

Goodwill and Intangible Assets

Goodwill is the excess of purchase price over the fair value of net assets acquired in business acquisitions. Goodwill is subject to, at a minimum, an annual impairment assessment of its carrying value. Additional impairment assessments would be performed if events and circumstances warranted such additional assessments during the year. Goodwill impairment is deemed to exist if the net book value of the Company's reporting unit exceeds its estimated fair value. Estimated fair value of the Company's reporting unit is determined utilizing the value implied by the Company's year-end quoted stock price. There were no impairments recorded on goodwill during the years ended June 30, 2015, 2014 or 2013.

The Company has one reporting unit. The reporting unit includes its product lines, the base technology for which was obtained as part of our November 2002 acquisition of Unित्रact Syringe Pty Limited and the manufacturing capability which was obtained in our January 2007 acquisition of Integrated BioSciences, Inc. In estimating the reporting unit's fair value for purposes of the fiscal year 2015 impairment assessment, management compared the carrying value of the reporting unit to the Company's market capitalization as of

June 30, 2015, which is its annual impairment testing date. The market capitalization of approximately \$283.7 million, based on the quoted stock price on NASDAQ was in excess of the Company's stockholders' deficit of \$17.9 million. Management also considered that market capitalization through early September 2015 continued to be in excess of the carrying value.

Definite-lived intangible assets include patents which are amortized on a straight-line method over their estimated useful lives of 15 years and are included in other assets. The Company reviews intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. When factors indicate a possible impairment, if the sum of the estimated undiscounted future cash flows expected to result from the use and eventual disposition of an asset is less than the carrying amount of the asset, an impairment may be recognized. Measurement of an impairment loss is based on the excess of the carrying value of the asset over its fair value. There were no impairments recorded on intangible assets during the years ended June 30, 2015, 2014 or 2013.

Deferred Financing Costs

Deferred financing costs are included in other assets on the consolidated balance sheets and consist of costs incurred in connection with debt financings. These costs are amortized and included in interest expense over the term of the related debt using the effective interest rate method.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Deferred tax assets are recorded to the extent the Company believes they will more likely than not be realized. In making such determinations, the Company considers all available positive and negative evidence, including future reversals of existing temporary differences, projected future taxable income, tax planning strategies and recent financial operations. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected more likely than not to be realized.

The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. The Company's policy is to include interest and penalties related to uncertain tax positions within the provision (benefit) for income taxes within the Company's consolidated statements of operations and comprehensive loss.

Fair Value of Financial Instruments

In accordance with Accounting Standards Codification ("ASC") 820, Fair Value Measurements and Disclosures, the Company measures fair value based on a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. The fair value hierarchy is broken down into three levels based on the source of inputs.

The carrying value of financial instruments such as accounts receivable, accounts payable and accrued expenses are reasonable estimates of their fair value because of the short maturity of these items. The Company believes that the current carrying amount of its long-term debt approximates fair value because the interest rates on these instruments are similar to those rates that the Company would currently be able to receive for similar instruments of comparable maturity.

The Company has elected to measure its royalty liability at fair value in accordance with ASC 825, Financial Instruments. The fair value of the royalty liability is based on significant inputs not observable in the market, which require it to be reported as a Level 3 liability within the fair value hierarchy. The valuation uses a methodology and assumptions that the Company believes would be made by a market participant. In particular, the valuation analysis uses a discounted cash flow methodology under the income approach based on the present value sum of payments to be made in the future. The fair value of the royalty liability is estimated by applying a risk adjusted discount rate to the adjusted royalty revenue stream. These fair value estimates are most sensitive to changes in the payment stream.

Share-Based Compensation

The Company grants equity awards to its employees, directors, consultants and service providers. Certain employee and director awards vest over stated vesting periods and others also require achievement of specific performance or market conditions. The Company expenses the grant-date fair value of awards to employees and directors over their respective vesting periods. To the extent that employee and director awards vest only upon the achievement of a specific performance condition, expense is recognized over the period from the date management determines that the performance condition is probable of achievement through the date they are expected to be met. Awards granted to consultants and service providers are sometimes granted for past services, in which case their fair value is expensed on their grant date, while other awards require future service, or the achievement of performance or market conditions. Timing of expense recognition for consultant awards is similar to that of employee and director awards; however, aggregate expense is re-measured each quarter-end based on the then fair value of the award through the vesting date of the award. The Company estimates the fair value of stock options using the Black-Scholes option-pricing model, with the exception of market-based grants, which are valued based on the Monte Carlo option pricing model. Option pricing methods require the input of highly subjective assumptions, including the expected stock price volatility.

Foreign Currency Translation

The Australian dollar is the functional currency for the Company's Australian operations. Assets and liabilities denominated in foreign currencies are translated into U.S. dollars at the rate of exchange existing at the end of the period. Revenues and expenses are translated at the average exchange rates during the applicable period. Adjustments resulting from these translations are recorded in accumulated other comprehensive income within the Company's consolidated balance sheets and will be included in income upon sale or liquidation of the foreign investment. Gains and losses from foreign currency transactions, denominated in a currency other than the functional currency, are recorded in other income within the Company's consolidated statements of operations and comprehensive loss and aggregated less than \$0.1 million for each of the years ended June 30, 2015, 2014 and 2013.

Comprehensive Loss

Comprehensive loss includes net loss and other comprehensive loss (income). The Company's other comprehensive loss (income) consists only of foreign currency translation adjustments.

Revenue Recognition

The Company recognizes revenue from industrialization and development fees, licensing fees and product sales. The Company recognizes revenue from sales of products at the time of shipment when title passes to the customer. The Company recognizes up front, non-refundable fees ratably over the expected life of the related agreement. Revenue from industrialization and development fees is recognized as services are rendered or upon achievement of the "at risk" substantive milestone events, which represent the culmination of the earnings process related to such events. Substantive milestones can include specific deliverables such as product design, prototype availability, user tests, manufacturing proof of principle and the various steps to complete the

industrialization of the product. The terms of these contracts provide for customer payments to be made as services are rendered or substantive milestones are achieved. The Company considers whether a milestone is substantive at the inception of the agreement. The consideration earned from the achievement of a milestone must meet all of the following criteria to be considered substantive:

- It is commensurate with either of the Company's performance to achieve the milestone, or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company's performance to achieve the milestone;
- It relates solely to past performance; and
- It is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

Payment terms are considered to be standard commercial terms. Revenue is recognized when each substantive milestone has been achieved and the Company has no future performance obligations related to the substantive milestone. Fees for completed, substantive milestones, which are dependent upon customer acceptance for non-refundable payment or, if paid, are refundable pending customer acceptance are recognized upon customer acceptance or the termination of refund rights.

Advertising Costs

Advertising costs are expensed in the period incurred. The Company incurred total advertising costs of \$0.2 million for each of the years ended June 30, 2015, 2014 and 2013.

Research and Development Costs

Research and development expenses consist primarily of payroll and related personnel expenses (including share-based compensation expense), fees paid to external service providers, costs of materials, components and supplies, costs for facilities, tooling and equipment and costs related to developing prototype products and samples used for various evaluation, testing and related activities for existing and potential customers. Research and development expenses are included in operating expenses when incurred. Research and development expenses include costs related to the ongoing development and expansion of the Company's broad portfolio of injectable drug delivery systems as well as costs incurred in relation to customization, industrialization and development agreements with its customers. These costs are not segregated from the overall research and development costs as they are not readily distinguishable from the rest of the Company's ongoing research and development expenses.

Interest Expense

The Company recognizes interest expense in the consolidated statements of operations and comprehensive loss for all debt instruments using the effective interest method. The effective interest method is a method of calculating the amortized cost of a financial liability and of allocating the interest expense over the relevant period. The effective interest rate is the rate that exactly discounts the estimated future cash payments through the expected life of the financial instrument to the net carrying amount of the financial liability. The application of the method has the effect of recognizing expense payable on the instrument evenly in proportion to the amount outstanding over the period to maturity or repayment. In calculating the effective interest rate, the Company estimates cash flows considering all contractual terms of the financial instrument, including fees for early redemption and all other premiums and discounts.

Net Loss Per Share

Basic net loss per share is computed as net loss divided by the weighted average number of shares outstanding during the period. Diluted net earnings per share reflect the potential dilution that could occur from

common stock issued through common stock equivalents. The dilutive effect of potential common stock, consisting of non-participating restricted stock and outstanding options to purchase common stock, is calculated using the treasury stock method.

Unvested share-based payment awards that contain nonforfeitable rights to dividends or dividend equivalents, whether paid or unpaid, are considered participating securities and are included in the computation of net loss per share according to the two class method if the impact is dilutive. Shares of the Company's unvested restricted stock are considered participating securities. However, in the event of a net loss, participating securities are excluded from the calculation of both basic and diluted net loss per share.

Business Segments

The Company operates in one reportable segment, which includes the design, development and manufacture of injectable drug delivery systems. Revenues by geographic location based on location of customer are as follows:

	Years Ended June 30,		
	2015	2014	2013
	(In thousands)		
Domestic	\$ 9,834	\$ 5,702	\$ 120
International	3,324	8,987	2,623
	<u>\$13,158</u>	<u>\$14,689</u>	<u>\$2,743</u>

Reclassifications

Certain prior year amounts in the consolidated financial statements have been reclassified to conform to the current year presentation.

Recently Issued Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board ("FASB") issued ASU 2013-11, "Income Taxes — Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists" ("ASU 2013-11") which is part of Accounting Standards Codification ("ASC") 740: Income Taxes. The new guidance requires an entity to present an unrecognized tax benefit and a net operating loss carryforward, a similar tax loss, or a tax credit carryforward on a net basis as part of a deferred tax asset, unless the unrecognized tax benefit is not available to reduce the deferred tax asset component or would not be utilized for that purpose, then a liability would be recognized. ASU 2013-11 was adopted effective July 1, 2014 and this guidance did not materially impact the Company's financial condition, results of operations or cash flows.

In May 2014, FASB issued ASU 2014-09 "Revenue from Contracts with Customers". The guidance requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to a customer. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. In August 2015, the FASB issued ASU 2015-14 "Revenue from Contracts with Customers" which deferred the effective date of ASU 2014-09 for all entities by one year to annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. Early application is permitted only as of annual periods beginning after December 15, 2016, including interim reporting periods within that reporting period. With the deferral, the new standard is effective for the Company, on July 1, 2018, with early adoption permitted one year prior. The standard permits the use of either the retrospective or cumulative effect transition method. The Company has not selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

In June 2014, FASB issued ASU 2014-12 “Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period” which is part of ASC 718: Compensation-Stock Compensation. The guidance requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition and not be reflected in the estimate of the grant-date fair value of the award. The guidance is effective for annual periods beginning after December 15, 2015. The guidance can be applied prospectively for all awards granted or modified after the effective date or retrospectively to all awards with performance targets outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. The Company does not expect a material impact on its financial condition, results of operations or cash flows from the adoption of this guidance.

In August 2014, FASB issued ASU 2014-15 “Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern”. The guidance requires an entity to perform a going concern assessment by evaluating its ability to meet its obligations for a look-forward period of one year from the financial statement issuance date. Disclosures are required if it is probable an entity will be unable to meet its obligations within the look-forward period. Incremental substantial doubt disclosure is required if the probability is not mitigated by management’s plans. The guidance is effective for all entities for the first annual period ending after December 15, 2016 and interim periods thereafter. Early application is permitted. The Company is currently evaluating the impact this guidance will have on its financial disclosures; however, as the guidance only impacts disclosure, the adoption of this guidance is not expected to have any impact on the Company’s financial condition, results of operations and cash flows.

In April 2015, FASB issued ASU 2015-03 “Simplifying the Presentation for Debt Issuance Costs”. The guidance requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The guidance is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. The Company is currently evaluating the impact this guidance will have on its financial statement presentation and any disclosures.

4. Equity Transactions and Share-Based Compensation

During the year ended June 30, 2013, the Company issued 6,154,000 shares of common stock and raised \$18.8 million, net of issuance costs, through an underwritten registered public offering.

During the year ended June 30, 2013, the Company entered into the old Sales Agreement, pursuant to which the Company, from time to time, issued and sold shares of common stock having an aggregate offering price of up to \$45.0 million. During the years ended June 30, 2014 and 2013, the Company issued 5,012,153 shares and 4,990,434 shares of common stock and raised net proceeds of \$16.9 and \$14.3 million, respectively, under the old Sales Agreement. During the year ended June 30, 2015, the Company issued 5,808,800 shares of common stock and raised net proceeds of \$12.4 million under the old Sales Agreement.

During the year ended June 30, 2013, the Company issued 4,460,966 shares of common stock for net proceeds of \$9.6 million, net of issuance costs, pursuant to a securities purchase agreement. In connection with the securities purchase agreement, the Company issued two warrants to purchase an aggregate of 1,586,988 shares of common stock. The warrants are exercisable at \$3.00 per share and will expire five years from the date of grant. The warrants contain exchange features whereby the warrant holders can exchange the warrants for cash or common stock equal to the value of the warrants at the time of exchange, which value is based upon a contractual formula. Based on the terms of the agreements, the Company has determined that the warrants should be classified as a liability. As of March 31, 2013, the Company recorded a liability of \$3.0 million related to the negotiated value of the warrants. In April 2013, the exchange feature was exercised for one of the warrants and a total of 1,424,220 shares of common stock were issued in settlement of a warrant to purchase 1,486,988 shares of common stock and the related warrant liability of \$2.8 million was reclassified to equity. As of June 30, 2013,

one warrant to purchase 100,000 shares of common stock remained outstanding. During the year ended June 30, 2014, the warrant was exercised in exchange for 19,471 shares of common stock and the related warrant liability of \$0.4 million was reclassified to equity.

During the year ended June 30, 2013, the Company granted certain directors 75,000 shares of common stock that were vested upon issuance, of which 45,000 shares may not be sold or transferred until such time as the director leaves the board of directors for any reason, including a change in control. The weighted average grant date fair value of the shares was \$3.17 per share.

During the year ended June 30, 2014, the Company granted certain directors 227,500 shares of common stock which may not be sold or transferred until such time as the director leaves the board of directors for any reason, including a change in control, or other permitted circumstances. The weighted average grant date fair value of the shares was \$3.95 per share.

During the year ended June 30, 2015, the Company granted certain directors 175,000 shares of common stock which may not be sold or transferred until such time as the director leaves the board of directors for any reason, including a change in control, or other permitted circumstances. The weighted average grant date fair value of the shares was \$2.83 per share.

During the year ended June 30, 2015, the Company issued 12,650,000 shares of common stock and raised \$44.7 million, net of issuance costs, through an underwritten registered public offering. The Company intends to use the proceeds from the public offering for investments in its plant, equipment, systems and personnel to further develop its manufacturing and operational capabilities to satisfy current and future customer orders and for working capital and other general corporate purposes.

The Company recognized share-based compensation expense related to equity awards to employees, directors, consultants and service providers of \$11.8 million, \$8.3 million and \$13.3 million during the years ended June 30, 2015, 2014 and 2013, respectively.

As of June 30, 2015, the total compensation cost related to all non-vested awards not yet recognized was \$26.8 million. This amount is expected to be recognized over a remaining weighted average period of 2.10 years.

Stock Options and Warrants

The Company has granted stock options to certain employees and directors under the Employee Share Option Plan (the “Plan”). The Plan is designed to assist in the motivation and retention of employees and directors and to recognize the importance of employees and directors to the long-term performance and success of the Company. The Company has also granted stock options to certain service providers outside of the Plan. The majority of the options to purchase common stock vest on the anniversary of the date of grant, which ranges from one to three years. Additionally, certain stock options vest upon the closing price of the Company’s common stock reaching certain minimum levels, as defined in the agreements. Share-based compensation expense related to options granted to employees and directors is recognized on a straight-line method over the related vesting term. Share-based compensation expense related to options granted to service providers is recognized ratably over each vesting tranche of the options.

During the year ended June 30, 2010, the Company adopted the 2009 Stock Incentive Plan (the “Stock Incentive Plan”). The Stock Incentive Plan initially provided for a maximum of 6,000,000 shares of common stock to be reserved for the issuance of stock options and other stock-based awards. Commencing on January 1, 2012, and on each January 1st thereafter, through January 1, 2014, the share reserve automatically adjusted so that it was equal to 17.5% of the weighted average number of shares of common stock outstanding reduced by the sum of any shares of common stock issued under the Stock Incentive Plan and any shares of common stock subject to outstanding awards under the Stock Incentive Plan.

During the year ended June 30, 2015, the Stock Incentive Plan was amended and restated (the “Amended and Restated 2009 Stock Incentive Plan” or “Amended Stock Plan”) to change how the number of shares of common stock that may be issued under the Amended Stock Plan is calculated, to increase the number of shares of common stock available for issuance under the Amended Stock Plan by 10.0 million and to reapprove the Amended Stock Plan for purposes of refreshing the stockholder approval requirement.

The following is a summary of activity related to stock options held by employees and directors during the year ended June 30, 2015:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (In Years)	Aggregate Intrinsic Value (In thousands)
Outstanding as of July 1, 2014	3,922,411	\$4.67		
Cancelled	(170,257)	5.43		
Expired	(1,234,000)	6.38		
Exercised	(10,000)	2.33		
Outstanding as of June 30, 2015	<u>2,508,154</u>	<u>\$3.78</u>	<u>6.4</u>	<u>\$—</u>
Exercisable as of June 30, 2015	<u>1,908,154</u>	<u>\$3.83</u>	<u>6.2</u>	<u>\$—</u>

The following is a summary of activity related to stock options and warrants held by persons other than employees and directors during the year ended June 30, 2015:

	Number of Options and Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (In Years)	Aggregate Intrinsic Value (In thousands)
Outstanding as of July 1, 2014	2,050,000	\$4.52		
Expired	(1,000,000)	4.86		
Outstanding as of June 30, 2015	<u>1,050,000</u>	<u>\$4.20</u>	<u>1.3</u>	<u>\$23</u>
Exercisable as of June 30, 2015	<u>1,050,000</u>	<u>\$4.20</u>	<u>1.3</u>	<u>\$23</u>

The aggregate intrinsic value is defined as the difference between the market value of the Company’s common stock as of the end of the period and the exercise price of the in-the-money stock options. The total intrinsic value of stock options exercised during the years ended June 30, 2015, 2014 and 2013 was \$0.1 million, \$1.8 million and \$0.1 million, respectively.

The Company currently uses authorized and unissued shares to satisfy stock option exercises.

The weighted average fair value of stock options granted during the years ended June 30, 2014 and 2013 was \$1.67 and \$1.69 per share, respectively. There were no stock options granted during the year ended June 30, 2015.

The following is a summary of outstanding and exercisable stock options held by employees and directors as of June 30, 2015:

Range of Exercise Prices	Outstanding Options			Exercisable Options		
	Outstanding as of June 30, 2015	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (In Years)	Exercisable as of June 30, 2015	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (In Years)
\$0.00 — \$5.00	2,190,000	\$3.50	6.8	1,590,000	\$3.46	6.6
\$5.01 — \$7.00	318,154	5.69	4.2	318,154	5.69	4.2
	<u>2,508,154</u>	<u>\$3.78</u>	<u>6.4</u>	<u>1,908,154</u>	<u>\$3.83</u>	<u>6.2</u>

The following is a summary of outstanding and exercisable stock options held by persons other than employees and directors as of June 30, 2015:

Range of Exercise Prices	Outstanding Options			Exercisable Options		
	Outstanding as of June 30, 2015	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (In Years)	Exercisable as of June 30, 2015	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (In Years)
\$0.00 — \$2.00	150,000	\$2.00	0.8	150,000	\$2.00	0.8
\$2.01 — \$6.00	900,000	4.57	1.4	900,000	4.57	1.4
	<u>1,050,000</u>	<u>\$4.20</u>	<u>1.3</u>	<u>1,050,000</u>	<u>\$4.20</u>	<u>1.3</u>

The Company used the following weighted average assumptions in calculating the fair value of options and warrants granted during the year ended June 30, 2014 and 2013:

	2014	2013
Number of stock options granted	500,000	810,000
Expected dividend yield	0%	0%
Risk-free interest rate	1.52%	1.03%
Expected volatility	55%	55%
Expected life (in years)	5.5	5.44

The assumptions noted above for the year ended June 30, 2013 do not include amounts related to the warrants to purchase 1,586,988 shares of common stock issued in connection with the Securities Purchase Agreement.

The fair value of each stock option was estimated at the grant date using the Black-Scholes option pricing model. The Company has not historically paid dividends to its stockholders and, as a result, assumed a dividend yield of 0%. The risk free interest rate is based upon the rates of U.S. Treasury bonds with a term equal to the expected term of the option. The expected volatility used to value options granted after January 27, 2010 is based upon a blended rate of the historical share price of the Company's stock on the Australian Securities Exchange and the volatility of peer companies traded on U.S. exchanges operating in the same industry as the Company. The expected term of the options to purchase common stock issued to employees and directors is based upon the simplified method, which is the mid-point between the vesting date of the option and its contractual term unless a reasonable alternate term is estimated by management. The expected term of the options to purchase common stock issued to consultants and service providers is based on the contractual term of the awards.

Restricted Stock

The Company has granted shares of restricted stock to certain employees, directors and consultants under the Amended Stock Incentive Plan. During the period prior to vesting, the holder of the non-vested restricted

stock will have the right to vote and the right to receive all dividends and other distributions declared. All non-vested shares of restricted stock are reflected as outstanding; however, they have been excluded from the calculation of basic earnings per share.

For employees, the fair value of restricted stock is measured on the date of grant using the price of the Company's common stock on that date. Share-based compensation expense for restricted stock issued to employees is recognized on a straight-line basis over the requisite service period, which is generally the longest vesting period. For restricted stock granted to consultants, the fair value of the awards will be re-valued on a quarterly basis and marked to market until vested. Share-based compensation expense for restricted stock issued to consultants is recognized ratably over each vesting tranche.

During the year ended June 30, 2015, the shareholders approved the issuance of 4,000,000 shares of restricted stock to the Company's Chairman and Chief Executive Officer. The restricted stock was granted on November 14, 2014 and is subject to performance-based vesting and also contains service-based clawback provisions. The performance-based vesting will become satisfied based upon the trading price of the Company's common stock reaching certain minimum levels on NASDAQ for a minimum of 20 out of 30 consecutive trading days, which range from \$6.00 to \$12.00 per share. The restricted stock was valued at \$1.885 per share on the grant date using a Monte Carlo simulation model which is being expensed ratably over the projected vesting period, which is approximately 2.6 years. The restricted stock would be forfeited to the extent not vested on the fifth anniversary of the grant date. In addition, if prior to the fourth anniversary of the grant date he resigns from employment or is terminated for cause, a specified percentage of the previously vested shares would be required to be returned, which ranges from 100% prior to the first anniversary of the grant date to 25%, on or after the third anniversary of the grant date.

The following is a summary of activity related to restricted stock awards during the year ended June 30, 2015:

	Number of Restricted Stock Awards	Weighted Average Grant Date Fair Value
Unvested as of July 1, 2014	2,436,061	\$3.42
Granted	9,507,434	2.83
Vested	(947,344)	3.54
Cancelled	(264,375)	3.42
Unvested as of June 30, 2015	<u>10,731,776</u>	<u>\$2.89</u>

The total fair value of shares vested during the years ended June 30, 2015, 2014 and 2013 was \$3.4 million, \$6.0 million and \$18.2 million, respectively.

5. Property, Plant and Equipment

Property, plant and equipment consist of the following:

	June 30,	
	2015	2014
	(In thousands)	
Building	\$ 32,359	\$ 32,188
Machinery and equipment	27,530	21,224
Computer software	2,910	2,675
Furniture and fixtures	1,345	610
Construction in progress	17,601	9,119
Land	2,036	2,036
Leasehold improvements	270	166
	84,051	68,018
Less: accumulated depreciation and amortization	(17,903)	(13,430)
Property, plant and equipment, net	<u>\$ 66,148</u>	<u>\$ 54,588</u>

Construction in progress as of June 30, 2015 and 2014 consisted of amounts incurred in connection with machinery and equipment and facility related costs, including capitalized interest.

6. Goodwill

The changes in the carrying amount of goodwill during the years ended June 30, 2014 and 2015 are as follows:

	(In thousands)
Balance as of July 1, 2013	\$11,498
Foreign currency translation	332
Balance as of June 30, 2014	11,830
Foreign currency translation	(2,145)
Balance as of June 30, 2015	<u>\$ 9,685</u>

7. Accrued Expenses

Accrued expenses consist of the following:

	June 30,	
	2015	2014
	(In thousands)	
Accrued payroll and other employee related expenses	\$2,781	\$2,103
Accrued other	2,293	1,236
Total accrued expenses	<u>\$5,074</u>	<u>\$3,339</u>

8. Commitments and Contingencies

The Company leases certain facilities, office equipment and automobiles under non-cancellable operating leases that expire on various dates through June 2022. The future minimum lease payments related to the Company's non-cancellable operating lease commitments that have initial or remaining non-cancellable lease terms in excess of one year as of June 30, 2015 were as follows:

<u>For the Year Ending June 30,</u>	<u>(In thousands)</u>
2016	\$1,237
2017	1,244
2018	1,256
2019	1,259
2020	1,283
Thereafter	2,639
	<u>\$8,918</u>

Rental expenses under operating leases during the years ended June 30, 2015, 2014 and 2013 were \$0.9 million, \$0.6 million and \$0.3 million, respectively.

From time to time, the Company is involved in various legal proceedings, claims, suits and complaints arising out of the normal course of business. Based on the facts currently available to the Company, management believes that these claims, suits and complaints are adequately provided for, covered by insurance, without merit or not probable that an unfavorable outcome will result.

A former employee, Talbot Smith, who was terminated for cause by Unilife, filed a civil complaint in the United States District Court of the Eastern District of Pennsylvania on August 30, 2013, and an amended complaint on March 5, 2014, alleging that he was wrongly terminated in retaliation for making allegations about the Company's compliance practices. We and various third parties, including law firms and regulatory consulting firms, investigated the allegations made by Mr. Smith and determined that his allegations were without merit, and the Company brought counterclaims against Mr. Smith. Discovery concluded and in February 2015 we filed our motions for summary judgment with the District Court, seeking entry of judgment in favor of the Company on the claims brought by Mr. Smith against the Company, and entry of judgment in favor of the Company on the claims brought by the Company against Mr. Smith.

Following the discovery process and while the Company's motions for summary judgment were pending before the District Court, on August 18, 2015, Mr. Smith dismissed his claims against the Company with prejudice.

As previously disclosed, subsequent to the filing of the OSHA complaint by Mr. Smith, we received a subpoena from the staff of the U.S. Securities and Exchange Commission (the "Staff") requesting the Company to provide certain information to the Staff, which is generally consistent with the meritless allegations made by Mr. Smith in his OSHA complaint. In his complaint filed in the United States District Court for the Eastern District of Pennsylvania, Mr. Smith stated that he provided the Staff with information about his allegations in July and August 2012. The Company responded to that subpoena and has received additional subpoenas from the Staff, requesting additional information consistent with the first subpoena. The Company is cooperating fully with the Staff and has provided the requested information.

On January 8, 2014, the Company was served with a derivative complaint filed in the Delaware Chancery Court by Cambridge Retirement System, a purported stockholder of the Company, against its Board of Directors to recover allegedly "excessive and wasteful" compensation paid to the non-executive directors since 2010. The Company believes that these allegations are baseless and without merit and the Company and the directors are defending themselves vigorously. In February 2014, the Company filed a motion to dismiss the complaint in lieu

of an answer. On June 26, 2014, the Court granted the Company's motion to dismiss with respect to the directors' equity grants, but denied the motion with respect to their cash compensation. The Company filed an answer to the remaining claims on July 11, 2014. On June 4, 2015, the parties entered into a Memorandum of Understanding agreeing to the basic terms of a non-monetary settlement of the action. The parties are negotiating the final terms of a stipulated settlement to be submitted to the Court for approval.

The Company does not believe there will be any material impact to the Company or its business as a result of the SEC or Cambridge Retirement Fund matters.

9. Long-Term Debt

Long-term debt consists of the following:

	June 30,	
	2015	2014
	(In thousands)	
10.25% term loan, due March 2020	\$55,518	\$33,457
Amended Royalty Agreement liability	9,930	6,400
6.00% mortgage loans, due December 2031	12,812	13,228
5.00% Commonwealth of Pennsylvania financing authority loan, due January 2021	2,033	2,087
Other	142	276
	80,435	55,448
Less: current portion of long-term debt	775	613
Total long-term debt	<u>\$79,660</u>	<u>\$54,835</u>

Term Loan

On March 12, 2014, (the "Closing Date"), the Borrower entered into a credit agreement with the Lender. Pursuant to and subject to the terms of the credit agreement, the Lender agreed to provide term loans to the Borrower in the aggregate principal amount of up to \$60.0 million. A first tranche loan of \$40.0 million was drawn on the Closing Date and a further two tranches each of \$10.0 million were committed by the Lender and were to be funded on each of December 15, 2014 and June 15, 2015, subject to and in accordance with the terms of the credit agreement. On September 30, 2014, the Borrower entered into a First Amendment to the Credit Agreement to accelerate the funding of the two additional tranches pursuant to which it received the proceeds from the first \$10.0 million tranche on October 1, 2014 and the proceeds from the second \$10.0 million tranche on November 10, 2014.

The Loan bears interest at 9.25% per annum plus the greater of three-month LIBOR or 1.0%, payable in cash quarterly and as otherwise described in the Amended Credit Agreement. A default interest rate of 14.25% per annum plus the greater of three-month LIBOR or 1.0% shall apply during the existence of a default under the Amended Credit Agreement. The Loans will be interest-only until March 12, 2020 (the "Maturity Date").

Unless the loan facility is otherwise terminated earlier pursuant to the terms of the Amended Credit Agreement, the Borrower is required to repay in full the unpaid principal amount of the Loans drawn down, together with all accrued and unpaid interest thereon plus a 10.0% repayment premium on Maturity Date. The Borrower can make voluntary repayments at any time of any unpaid principal amount of the Loans, plus a 10.0% repayment premium. The Borrower must make mandatory prepayments in certain prescribed circumstances, including, without limitation, certain dispositions of assets and certain casualty events. In such events, the Borrower must prepay to Lender 100% of the net cash proceeds received.

The obligations of the Borrower under the Amended Credit Agreement are guaranteed by the Company and each of its subsidiaries and the Amended Credit Agreement is secured by the assets of the Company and its subsidiaries. The security interests granted by Borrower, the Company, Unilife Cross Farm LLC (“Cross Farm”), Unilife Medical Solutions Limited (“USML”) and Unitract Syringe Pty Limited (“Unitract Syringe”) are evidenced by, among other things, the Pledge and Security Agreement, dated as of March 14, 2014, by the Borrower, the Company, Cross Farm, USML, and Unitract Syringe in favor of Lender, for itself and as agent for Royalty Opportunities S.A.R.L. (“ROS”), the Mortgage and Security Agreement, dated March 12, 2014, by and between Cross Farm and Lender, for itself and as agent of ROS, and the General Security Deed, dated as of March 12, 2014, by Unitract Syringe, USML, and the Company in favor of the Lender, for itself and as agent of ROS.

The Amended Credit Agreement also contains certain customary covenants, as well as covenants relating to achieving minimum cash revenue targets at the end of each calendar year, maintaining a minimum liquidity target of \$5.0 million, and the execution of certain customer and employment agreements in form and substance satisfactory to lender. In the event of default, Borrower must prepay to Lender any unpaid principal amount of the loans drawn down, together with all accrued and unpaid interest thereon plus a 10.0% repayment premium. An event of default could also result in the Lender enforcing its security over the assets of Borrower, the Company, Cross Farm, USML and Unitract Syringe in accordance with the terms of the OrbiMed Credit Agreement and the related security agreements. On June 30, 2015, the Company entered into a Second Amendment to the Credit Agreement to remove the minimum cash revenue target for the six month period ended June 30, 2015. As of and for the year ended June 30, 2015, the Company is in compliance with all the loan covenants set forth in the Amended Credit Agreement. However, there can be no assurance that the Company will be able to maintain the minimum liquidity target or achieve the minimum cash revenue covenants during the 12-month period from June 30, 2015.

In connection with the credit agreement, the Borrower entered into a royalty agreement (the “Royalty Agreement”) with ROS which will entitle ROS to receive royalty payments. Concurrent with the First Amendment to the Credit Agreement, the Borrower entered into the First Amendment to the Royalty Agreement (the “Amended Royalty Agreement”). Pursuant to and subject to the terms of the Amended Royalty Agreement, Borrower has agreed to pay the Lender 3.875% on the first \$50.0 million of net sales (on a cash receipts basis as defined in the Amended Credit Agreement) in each fiscal year, plus 1.500% of net sales in excess of \$50.0 million and up to and including \$100.0 million in each fiscal year, plus 0.375% of net sales in excess of \$100.0 million in each fiscal year. Borrower has the right to buyout the Amended Royalty Agreement at any time on or before March 12, 2018 at a reduced amount. The lender has the right to exercise a put option upon the occurrence of an event of default upon which the Borrower would be required to pay the buyout amount under the Amended Royalty Agreement. The buy-out amount ranges from \$9.75 million to \$26.25 million (such amount to be determined based on when the buy-out or put option is exercised), less amounts previously paid by Borrower to Lender pursuant to the Amended Royalty Agreement. The Amended Royalty Agreement has a term commencing on the Closing Date and ending on the earlier of (i) the tenth anniversary of the Closing Date and (ii) the date of payment of the purchase price pursuant to the exercise of a put option by the Lender or the exercise of a buy-out option by the Borrower. As the Company has elected to value the Amended Royalty Agreement at fair value, the put option feature does not meet the criterion of ASC 815-15-25-1b and thus is not separated from the host contract and accounted for as a derivative instrument.

The Company determined that the Amended Credit Agreement and the Amended Royalty Agreement should be accounted for as two separate units. Accordingly, the Company allocated the proceeds from the Loans on a residual basis between the two units based on their relative fair values. As a result, on the Closing Date, the royalty liability was determined to have a fair value of \$7.0 million and the Loan was allocated the remaining proceeds of \$33.0 million. The \$20.0 million from the two additional tranches that were funded during the three months ended December 31, 2014 was reflected as incremental debt. The Loan will be accreted to the face value over the loan term based on the effective interest rate. The royalty liability will be adjusted to fair value on a quarterly basis. As of June 30, 2015, the fair value of the royalty liability was \$9.9 million.

There are cross-defaults in the Amended Credit Agreement, Metro Bank Loan and Keystone/CFA Loan, so that a default under one agreement could trigger a default under the others. Metro Bank, the Lender under the Amended Credit Agreement, Keystone Redevelopment Group, LLC and Commonwealth Financing Authority are parties to an intercreditor agreement.

Mortgage Loans

In October 2010, Cross Farm entered into the Loan Agreement with Metro Bank, pursuant to which Metro Bank provided Cross Farm with two mortgage loans in the amounts of \$14.25 million (“First Mortgage”) and \$3.75 million (“Second Mortgage”). The proceeds received were used to finance the purchase of land and construction of the Company’s corporate headquarters and manufacturing facility in York, Pennsylvania. In connection with the credit agreement, the Company entered into the Metro Bank Amendment pursuant to which the Second Mortgage due October 2020 was repaid. Cross Farm is paying principal and interest on the First Mortgage, with interest at a fixed rate of 6.00%.

The original Metro Bank loan documents contain certain customary covenants, including the maintenance of a debt service reserve account in the amount of \$2.4 million, classified as restricted cash on the consolidated balance sheet, which will remain in place until Cross Farm and Metro agree on the financial covenants. In addition the Company is required to maintain a cash balance of \$5.0 million inclusive of the \$2.4 million reserve account. The terms of the original Metro Bank loan documents allow the Company to use the debt service reserve account to pay monthly debt service on the mortgage loans, so long as the balance in the account is at least \$1.6 million and is replenished to \$2.4 million every six months. The Company is in compliance with its debt covenants as of and for the year ended June 30, 2015. However, there can be no assurance that the Company will be able to maintain the debt service reserve account balance for a period of 12 months from June 30, 2015. Cross Farm may prepay the loan without penalty. The U.S. Department of Agriculture has guaranteed \$8.0 million of the mortgage loan due December 2031. In connection with the First Mortgage, the Company has given Metro Bank a lien on the building and real estate and the debt service reserve account.

Secured Lending Facility

In August 2011, the Company entered into a Master Lease Agreement (the “Lease Agreement”) with Varilease Finance, Inc. (“Varilease”) for up to \$10.0 million of secured financing for production equipment for its Unifill syringe. Based on the Company’s continuing involvement throughout the term of the agreement and the integral nature of the production equipment, the transaction was being accounted for as a financing. Over the term of the Lease Agreement, the Company made 27 monthly installments based upon the amount drawn. This facility had an effective interest rate of 14.00%. The secured lending facility contained covenants and provisions for events of default customarily found in lease agreements.

As previously disclosed on September 30, 2013, Varilease and CCA Financial LLC (collectively, the “Lessors”) filed an action in the State of Michigan in the Circuit Court for the County of Oakland, Case No. 2013-136458-CK seeking a judgment confirming the terms of the lease. The Company removed the action to the U.S. District Court for the Eastern District of Michigan, Case No. 2:13-CV-14238-SFC-LJM, on October 4, 2013. Under the Lease Agreement, Lessors and the Company were to negotiate a buyout rate at the end of the two-year lease term, which Lessors represented to the Company during the lease negotiations would be 15% of the amount financed. When the Company notified Lessors that it wanted to exercise the buyout of the equipment, Lessors claimed a buyout rate significantly higher than 15%. Under the terms of the lease, if the parties were unable to agree on a buyout rate by the end of the lease term, the lease would automatically renew for an additional 12-month period and the Company would be responsible for another year of lease payments. Lessor’s action in Michigan state court asked the court to confirm that the parties were unable to agree on a buyout rate and therefore under the terms of the lease the lease was automatically extended for one year.

As previously disclosed, the Company also filed suit on September 30, 2013 against Lessors in the U.S. District Court for the Eastern District of Michigan, Case No. 2:13-cv-14174-SFC-LJM alleging, among other things, that Lessors fraudulently induced the Company into entering the lease by making misrepresentations about the buyout rate. The Company sought, among other things, to have the federal court enforce a 15% buyout rate and to enjoin Lessors from declaring a default under the lease and taking possession of the equipment for which the Company would have to impair the carrying value of assets. On October 17, 2013, in a stipulated order, the U.S. District Court ordered that the Company continue to make the same monthly payments under the lease, which as long as the Company made timely payments, Lessors shall not declare a default, and that Lessors were required to provide advance notice of a default.

As previously disclosed, the Company entered into a Confidential Mutual Release and Settlement Agreement (the "Definitive Settlement Agreement"), effective December 30, 2013, with the Lessors. The Definitive Settlement Agreement provided that it will obtain title to all equipment under the equipment lease upon the payment to the Lessors of approximately \$4.8 million over the next twelve months. In addition, under the Definitive Settlement Agreement the Company and the Lessors released each other from any and all claims related to the companion lawsuits, as well as dismissed such lawsuits. In connection with the Definitive Settlement Agreement, during the year ended June 30, 2014, the Company recognized \$3.6 million of interest expense representing the difference between the carrying value of the debt and the present value of the settlement amount.

During the year ended June 30, 2014, the Company paid \$4.7 million (including \$3.5 million with proceeds from the March 12, 2014 Credit Agreement) to the Lessors in satisfaction of the Company's remaining obligations under the Definitive Settlement Agreement. Effective March 12, 2014 the Lessors released all liens and security interest in all of the Company's assets subject to the Lease Agreement.

Commonwealth of Pennsylvania Financing Authority Loan

In December 2010, Cross Farm received a \$2.25 million loan from the Commonwealth of Pennsylvania for land and the construction of its current manufacturing facility. The loan bears interest at a rate of 5.00% per annum, matures in January 2021 and is secured by a third mortgage on the facility. In connection with the loan agreement, Cross Farm entered into an intercreditor agreement by which the Commonwealth of Pennsylvania agreed that it would not exercise its rights in the event of a default by Cross Farm without the consent of Metro Bank, which holds the first mortgage on the facility.

As of June 30, 2015, aggregate maturities of long-term obligations are as follows:

<u>For the Year Ending June 30,</u>	<u>(In thousands)</u>
2016	\$ 775
2017	552
2018	584
2019	618
2020	65,853
Thereafter	12,053
	<u>\$80,435</u>

10. Net Loss Per Share

The Company's net loss per share is as follows:

	Years Ended June 30,		
	2015	2014	2013
	(In thousands, except share and per share data)		
Numerator			
Net loss	\$ (90,849)	\$ (57,899)	\$ (63,198)
Denominator			
Weighted average number of shares used to compute basic net loss per share	112,194,900	98,062,664	81,165,773
Effect of dilutive options to purchase common stock	—	—	—
Weighted average number of shares used to compute diluted net loss per share	<u>112,194,900</u>	<u>98,062,664</u>	<u>81,165,773</u>
Basic and diluted net loss per share	<u>\$ (0.81)</u>	<u>\$ (0.59)</u>	<u>\$ (0.78)</u>

Due to the Company's net losses, unvested shares of restricted stock (participating securities) totaling 6,990,214, 2,687,775 and 4,909,091 were excluded from the calculation of basic and diluted net loss per share during the years ended June 30, 2015, 2014 and 2013, respectively.

In addition, stock options (non-participating securities) totaling 3,500,596, 4,642,725, and 7,996,935 during the years ended June 30, 2015, 2014 and 2013, respectively, were excluded from the calculation of diluted net loss per share as their effect would have been anti-dilutive. Certain of these stock options were excluded solely due to the Company's net loss position. Had the Company reported net income during the years ended June 30, 2015, 2014 and 2013, these shares would have had an effect of 145,735, 323,854, and 595,550 diluted shares, respectively, for purposes of calculating diluted net loss per share.

11. Income Taxes

For the years ended June 30, 2015, 2014 and 2013, income (loss) before income taxes consists of the following:

	Years Ended June 30,		
	2015	2014	2013
	(In thousands)		
Domestic	\$(89,617)	\$(58,784)	\$(63,752)
International	(1,232)	885	554
	<u>\$(90,849)</u>	<u>\$(57,899)</u>	<u>\$(63,198)</u>

Tax Rate Reconciliation

Income tax expense (benefit) is as follows:

	Years Ended June 30,								
	2015			2014			2013		
	Current	Deferred	Total	Current	Deferred	Total	Current	Deferred	Total
	(In thousands)								
U.S. Federal	\$—	\$(27,385)	\$(27,385)	\$—	\$(18,415)	\$(18,415)	\$—	\$(21,188)	\$(21,188)
State	—	(8,684)	(8,684)	—	(5,839)	(5,839)	—	(6,226)	(6,226)
International	—	(369)	(369)	—	266	266	—	177	177
Changes in valuation allowance	—	36,438	36,438	—	23,988	23,988	—	27,237	27,237
Income tax provision	<u>\$—</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$—</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$—</u>	<u>\$ —</u>	<u>\$ —</u>

Income tax expense (benefit) was \$0 for the years ended June 30, 2015, 2014 and 2013 and differed from the amounts computed by applying the U.S. federal income tax rate to pretax income (loss) as a result of the following:

	Years Ended June 30,		
	2015	2014	2013
Tax at U.S. statutory rate	(35)%	(35)%	(35)%
State taxes, net of federal benefit	(6)%	(6)%	(10)%
Non-deductible and non-taxable items	1%	—	1%
Change in valuation allowance	<u>40%</u>	<u>41%</u>	<u>44%</u>
	<u>0%</u>	<u>0%</u>	<u>0%</u>

Significant Components of Deferred Taxes

The tax effects of temporary differences and net operating losses that give rise to significant portions of deferred tax assets (liabilities) at June 30, 2015 and 2014 are presented below:

	June 30,	
	2015	2014
	(In thousands)	
Net operating loss carryforwards	\$ 110,876	\$ 89,362
Share-based compensation expense	20,548	16,532
Deferred revenue	6,951	—
Depreciation differences	4,324	2,399
Accruals/Reserves	3,517	2,104
Valuation allowance	<u>(146,216)</u>	<u>(110,397)</u>
Net deferred taxes	<u>\$ —</u>	<u>\$ —</u>

The valuation allowance for deferred tax assets as of June 30, 2015 and 2014 was \$146.2 million and \$110.4 million, respectively. The net change in the total valuation allowance was an increase of \$35.8 million. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible or prior to the expiration of the net operating loss carryforwards. Management considers the scheduled reversal of deferred tax liabilities (including the impact of available carryback and carryforward

periods), projected future taxable income, and tax-planning strategies in making the assessment as to the realizability of deferred tax assets. Based upon the level of historical taxable income and uncertainty regarding projections for future taxable income over the periods in which the deferred tax assets are deductible or can be utilized, management does not believe it is more likely than not that the Company will realize the benefits of these net operating losses and deductible temporary differences, as of June 30, 2015 and 2014. Therefore, a full valuation allowance has been provided as of June 30, 2015 and 2014. The amount of the net deferred tax assets considered realizable; however, could change if estimates of future taxable income during the carryforward period are increased.

As of June 30, 2015, the Company had net operating loss carryforwards for U.S federal, state and Australian income tax purposes of approximately \$256.4 million, \$256.4 million and \$22.7 million, respectively, which are available to offset future taxable income. The U.S. federal and state net operating loss carryforwards begin to expire in 2023. The Australian net operating losses do not expire.

The Australian net operating loss carryforwards of approximately \$22.7 million as of June 30, 2015 are subject to either the continuity of ownership or same business test (as defined under Australian tax law) that could limit or substantially eliminate the Company's ability to use these carryforwards. If there have been or will be changes in the Company's ownership or Australian business operations before these net operating loss carryforwards are utilized, they may be unavailable to reduce taxable income in the future. Further, under provision of the Internal Revenue Code, the utilization of a U.S corporation's federal and state net operating loss carryforwards may be significantly limited following a change in ownership of greater than 50% within a three-year period. The Company's federal and state net operating loss carryforwards may, therefore, be subject to an annual limitation. In addition, state net operating loss carryforwards may be further limited in Pennsylvania, which has a limitation equal to the greater of 20% of taxable income after modifications and apportionment, or \$5.0 million on state net operating losses utilized in any one year.

Management has evaluated the tax positions taken and has concluded that no liability for unrecognized tax benefits was required to be recorded for the years ended June 30, 2015, 2014 and 2013.

The Company files Australian, U.S. federal and state income tax returns. The Company is not subject to examination in any jurisdiction at this time. As a result of the net operating losses in prior years, the statute of limitations will remain open for a period following any utilization of net operating loss carryforwards and as such these periods remain subject to examination.

12. Employee Benefit Plan

The Company has a retirement savings 401(k) plan covering all U.S. employees (the "Plan"). Participating employees may contribute up to 100% of their pre-tax earnings, subject to the statutory limits. Effective January 1, 2012, the Company began a discretionary match to participant contributions into the Plan. The Company contributes fifty cents for each dollar a participant contributes, with a maximum of 3% of a participant's eligible earnings. The contributions made by the Company vest 50% upon two years of service and 100% upon three years of service. During the years ended June 30, 2015, 2014 and 2013, the Company paid \$0.5 million, \$0.3 million and \$0.3 million, respectively, to match employee contributions.

Additionally, during the years ended June 30, 2015 and 2013, the Company made a discretionary contribution of 1% of compensation, as defined, to all eligible employees, which amounted to \$0.1 million and \$0.1 million, respectively. During the year ended June 30, 2014, the Company did not make any discretionary contributions.

13. Revenue

The Company recognized \$13.2 million, \$14.7 million and \$2.7 million of revenue during the years ended June 30, 2015, 2014 and 2013, respectively.

During the year ended June 30, 2015, three customers accounted for 35%, 32% and 24% of consolidated revenue, respectively. During the year ended June 30, 2014, three customers accounted for 34%, 23% and 15% of consolidated revenue, respectively. During the year ended June 30, 2013, one customer accounted for 96% of consolidated revenue.

During the year ended June 30, 2015, revenue attributed to France accounted for 24% of consolidated revenue. During the year ended June 30, 2014, revenue attributed to Jordan and France accounted for 34% and 15% of consolidated revenue, respectively. During the year ended June 30, 2013, revenue attributed to France accounted for 96% of consolidated revenue.

During the year ended June 30, 2015, the Company recognized \$5.1 million of revenue related to substantive milestones, as follows:

The Company recognized \$2.7 million of revenue during the year ended June 30, 2015 pursuant to a feasibility agreement with a customer related to substantive milestones that were completed and accepted during the year. This agreement provides for certain customization and development activities for a drug delivery system to be performed for the customer and provides for payments to be made upon the completion of agreed-upon substantive milestones. An initial up-front payment of \$0.1 million was determined to be non-substantive and is being recognized on a straight-line basis over the expected term of the agreement. The remaining milestones were determined to be substantive at the time the agreement was entered into. Substantive milestones that were achieved during the year ended June 30, 2015 were as follows:

- \$0.4 million for development and delivery of a detailed project plan and a failure mode and effects analysis report;
- \$0.4 million for development and delivery of a report on preliminary product requirements and a risk management plan;
- \$1.5 million for development and delivery of human factor stimuli and related supporting documents; and
- \$0.4 million for development and delivery of additional human factor stimuli.

The remaining substantive milestones as of June 30, 2015 are as follows:

- \$0.5 million for development and delivery of additional human factor stimuli and a report on updated product requirements; and
- \$1.2 million for development and delivery of semi-functional prototypes and related feasibility, product requirement, and risk management reports.

The Company recognized \$0.9 million of revenue during the year ended June 30, 2015 pursuant to a feasibility agreement with a customer related to substantive milestones that were completed and accepted during the year. This agreement provides for certain customization and development activities for a drug delivery system to be performed for the customer and provides for payments to be made upon the completion of agreed-upon milestones. An initial up-front payment of \$0.5 million was determined to be non-substantive and is being recognized on a straight-line basis over the expected term of the agreement. The remaining milestones were determined to be substantive at the time the agreement was entered into. Substantive milestones that were achieved during the year ended June 30, 2015 were as follows:

- \$0.5 million for development and delivery of a report on device design options as well as potential manufacturing and assembly processes; and
- \$0.4 million for development and delivery of product samples and related supporting documents.

The remaining substantive milestone as of June 30, 2015 is as follows:

- \$0.2 million for development and delivery of a summary report related to testing and documentation activities.

The Company recognized \$0.3 million of revenue during the year ended June 30, 2015 pursuant to a feasibility agreement with a customer related to substantive milestones that were completed and accepted during the year. This agreement provides for certain customization and development activities for a drug delivery system to be performed for the customer and provides for payments to be made upon the completion of agreed-upon milestones. The milestones were determined to be substantive at the time the agreement was entered into. Substantive milestones that were achieved during the year ended June 30, 2015 were as follows:

- \$0.1 million for development and delivery of a report related to human factor studies and quality requirements;
- \$0.1 million for development and delivery of devices for compatibility and stability functional testing and related reporting; and
- \$0.1 million for development and delivery of devices for human factor study and related reporting.

There are no remaining substantive milestones under this agreement.

The Company recognized \$0.2 million of revenue during the year ended June 30, 2015 pursuant to a feasibility agreement with a customer related to substantive milestones that were completed and accepted during the year. This agreement provides for certain customization and development activities for a drug delivery system to be performed for the customer and provides for payments to be made upon the completion of agreed-upon milestones. The milestones were determined to be substantive at the time the agreement was entered into. Substantive milestones that were achieved during the year ended June 30, 2015 were as follows:

- \$0.1 million for development of customized devices for testing; and
- \$0.1 million for development and delivery of testing activities and related reporting.

There are no remaining substantive milestones under this agreement.

The Company recognized \$1.0 million of revenue during the year ended June 30, 2015 pursuant to a master services and supply agreement with a customer related to substantive milestones that were completed and accepted during the year. This agreement provides for certain customization and development activities for a drug delivery system to be performed for the customer and provides for payments to be made upon the completion of agreed-upon substantive milestones. An initial up-front payment of \$1.1 million was determined to be non-substantive and is being recognized on a straight-line basis over the expected term of the agreement. The remaining milestones were determined to be substantive at the time the agreement was entered into. Substantive milestones that were achieved during the year ended June 30, 2015 were as follows:

- \$0.2 million for development and delivery of a report defining device requirements;
- \$0.2 million for development and delivery of a report defining system requirements;
- \$0.2 million for development and delivery of devices for testing;
- \$0.2 million for development and delivery of a report defining production requirements; and
- \$0.2 million for development and delivery of components for a human factor study.

The remaining substantive milestones as of June 30, 2015 are as follows:

- \$0.6 million for development and delivery of a complete system layout;
- \$0.3 million for development and delivery of components for a human factor study;
- \$0.6 million for development and delivery of feasibility devices for testing;

- \$0.6 million for development and delivery of a clinical production process;
- \$0.4 million for development and delivery of components for a human factor study;
- \$0.4 million for completion of testing of assembly equipment;
- \$0.3 million for completion of filling process of clinical devices;
- \$0.4 million for delivery of containers for the filling process; and
- \$0.3 million for delivery of devices for clinical studies.

During the year ended June 30, 2015, the Company recognized \$8.1 million of revenue related to services rendered on a time and materials basis, proportional performance method and/or straight-line basis over the requisite service period pursuant to customer agreements to provide various customization and development services.

During the year ended June 30, 2014, the Company recognized \$8.1 million of revenue related to substantive milestones, as follows:

The Company recognized \$1.3 million of revenue during the year ended June 30, 2014 pursuant to a clinical supply agreement with a customer related to substantive milestones that were completed and accepted during the year. This agreement provides for the customization and development activities for a drug delivery system for a customer and provides for payments to be made upon the completion of agreed-upon milestones. The milestones were determined to be substantive at the time the agreement was entered into. Substantive milestones that were achieved during the year ended June 30, 2014 were as follows:

- \$0.4 million for development and delivery of devices to be used by the customer for compatibility testing;
- \$0.1 million for delivery of development and testing activities;
- \$0.6 million for delivery of development, testing and verification activities;
- \$0.1 million for development and delivery of testing materials; and
- \$0.1 million for certain support and testing activities.

There are no remaining substantive milestones under this agreement.

The Company recognized \$0.8 million of revenue during the year ended June 30, 2014 pursuant to a customization and commercial supply agreement with a customer related to a substantive milestone that was completed during the year. This agreement provides for the development of customized component parts for the customer to use in a drug-device combination product and provides for payments to be made upon the completion of agreed-upon milestones. The milestones were determined to be substantive at the time the agreement was entered into. The substantive milestone achieved during the year ended June 30, 2014 were as follows:

- \$0.8 million for customization and delivery of devices for compatibility and initial evaluation testing.

The remaining substantive milestones were as follows:

- \$0.8 million for delivery of devices for regulatory filings; and
- \$0.2 million for certain delivery of services supporting the customer's regulatory approval process.

The Company recognized \$0.7 million of revenue during the year ended June 30, 2014 pursuant to a materials transfer agreement with a customer related to substantive milestones that were completed during the year. This agreement provides for certain materials and related services to the customer and provides for

payments to be made upon the completion of agreed-upon milestones. The milestones were determined to be substantive at the time the agreement was entered into. The substantive milestones achieved during the year ended June 30, 2014 were as follows:

- \$0.4 million for delivery of testing materials;
- \$0.1 million for delivery of device design requirements report; and
- \$0.2 million for delivery of customization activities.

There were no remaining substantive milestones under this agreement.

The Company recognized \$0.3 million of revenue during the year ended June 30, 2014 pursuant to a collaborative research agreement with a customer related to substantive milestones that were completed during the year. This agreement provides for certain materials and related services to the customer and provides for payments to be made upon the completion of agreed-upon milestones. The milestones were determined to be substantive at the time the agreement was entered into. The substantive milestones achieved during the year ended June 30, 2014 were as follows:

- \$0.1 million for customization and delivery of devices for evaluation and user study purposes; and
- \$0.2 million for customization and delivery of devices for evaluation activities.

There were no remaining substantive milestones under this agreement.

The Company recognized \$5.0 million of revenue during the year ended June 30, 2014 pursuant to a binding license, development and supply agreement with a customer related to a substantive milestone that was completed during the year. This agreement provides for the development of customized devices and drug delivery systems for the customer to use in a drug-device combination product and provides for payments to be made upon the completion of agreed-upon milestones. The milestones were determined to be substantive at the time the agreement was entered into. The substantive milestone achieved during the year ended June 30, 2014 was as follows:

- \$5.0 million for customization, design and production of a prototype device for incorporation into a drug delivery system.

The remaining substantive milestones were as follows:

- \$5.0 million for delivery and acceptance of application for regulatory approval; and
- \$1.0 million each upon regulatory approval for up to 20 drug-delivery device combination products.

During the year ended June 30, 2014, the Company recognized \$4.3 million in revenue related to services rendered on a time and materials basis during the period pursuant to customer agreements to provide various customization and development services. During the year ended June 30, 2014, the Company recognized the final \$2.3 million of revenue related to its licensing agreement with Sanofi.

During the year ended June 30, 2013, the Company recognized \$2.6 million of revenue related to its licensing agreement with Sanofi and \$0.1 million from other sales.

14. Financial Instruments

The Company does not hold or issue financial instruments for trading purposes. The estimated fair values of the Company's financial instruments are as follows:

	June 30, 2015		June 30, 2014	
	Carrying Amount	Estimated Fair Value	Carrying Amount	Estimated Fair Value
	(In thousands)			
Amended Royalty Agreement liability	<u>\$9,930</u>	<u>\$9,930</u>	<u>\$6,400</u>	<u>\$6,400</u>

The carrying amount of the Company's cash equivalents, which includes certificates of deposit, accounts receivable, accounts payable and accrued expenses approximate fair value due to the short term maturities of these items. The estimated fair value of the Company's debt approximates its carrying value based upon the rates that the Company would currently be able to receive for similar instruments of comparable maturity.

The Company categorizes its assets and liabilities measured at fair value into a fair value hierarchy that prioritizes the inputs used in pricing the asset or liability. The three levels of the fair value hierarchy are as follows:

Level 1 — Quoted prices in active markets for identical assets or liabilities.

Level 2 — Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.

Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. This includes certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.

The levels in the fair value hierarchy within which a fair value measurement in its entirety falls is based on the lowest level input that is significant to the fair value measurement in its entirety.

The following table presents the Company's liabilities that are measured at fair value on a recurring basis for the periods presented:

	Fair Value Based On			
	Quoted Market Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Fair Value Measurements
	(In thousands)			
Amended Royalty Agreement liability:				
June 30, 2015	\$—	\$—	\$9,930	\$9,930
June 30, 2014	\$—	\$—	\$6,400	\$6,400

The following table presents the changes in the fair value of the level 3 financial instruments for the years ended June 30, 2015 and 2014.

	Royalty Agreement Liability
June 30, 2013	\$ —
Allocation of initial proceeds	7,000
Decrease in royalty liability	(600)
June 30, 2014	\$6,400
Royalty payments	(749)
Increase in royalty liability	4,279
June 30, 2015	\$9,930

Following is a description of the valuation methodology used to measure the Amended Royalty Agreement liability at fair value. There have been no changes in the methodology used during the year ended June 30, 2015:

The fair value is based on a discounted cash flow methodology under the income approach based on the present value sum of payments expected to be made in the future. The fair value is estimated by applying a risk adjusted discount rate to the expected royalty payment stream. These fair value estimates are most sensitive to changes in the payment stream and royalty rates.

15. Related Party Transactions

The Company has an agreement with a consulting firm, of which a member of the Company's board of directors is the principal. Under the terms of the agreement, the Company pays a fee for finance, accounting and secretarial consulting services within Australia. Amounts paid to the consulting entity during the years ending June 30, 2015, 2014 and 2013 were \$0.2 million, \$0.2 million and \$0.2 million, respectively.

16. Quarterly Results (unaudited)

	<u>Quarter Ended September 30, 2014</u>	<u>Quarter Ended December 31, 2014</u>	<u>Quarter Ended March 31, 2015</u>	<u>Quarter Ended June 30, 2015</u>
	(In thousands, except per share data)			
Year Ended June 30, 2015				
Revenues	\$ 1,380	\$ 5,403	\$ 2,921	\$ 3,454
Gross profit	1,380	5,403	2,921	3,454
Net loss	(22,262)	(19,387)	(23,105)	(26,095)
Basic and diluted loss per share	\$ (0.21)	\$ (0.18)	\$ (0.20)	\$ (0.22)
	<u>Quarter Ended September 30, 2013</u>	<u>Quarter Ended December 31, 2013</u>	<u>Quarter Ended March 31, 2014</u>	<u>Quarter Ended June 30, 2014</u>
	(In thousands, except per share data)			
Year Ended June 30, 2014				
Revenues	\$ 3,187	\$ 3,573	\$ 1,383	\$ 6,546
Gross profit	3,187	3,573	1,383	6,546
Net loss	(11,244)	(16,283)	(15,109)	(15,263)
Basic and diluted loss per share	\$ (0.12)	\$ (0.17)	\$ (0.15)	\$ (0.15)

Per share amounts for the quarters may not add to the annual amount due to differences in the weighted average common shares outstanding during the period.

17. Subsequent Events

On July 29, 2015, the Company entered into the New Sales Agreement with Cantor, pursuant to which it may, from time to time, issue and sell shares of common stock through Cantor as its sales agent, having an aggregate offering price of up to \$25.0 million, subject to certain limitations and conditions set forth in the New Sales Agreement.

Under the New Sales Agreement, Cantor may sell the shares by any method permitted by law deemed to be an "at-the-market" offering as defined in Rule 415 of the Securities Act of 1933, as amended, including, but not limited to, sales made directly on The NASDAQ Global Market, on any other existing trading market for the shares or to or through a market maker. Cantor has agreed in the new Sales Agreement to use its commercially reasonable efforts to sell the shares in accordance with the Company's instructions (including any price, time or size limit or other customary parameters or conditions the Company may impose). The Company is not obligated to make any sales of the shares under the New Sales Agreement.

The Company will pay Cantor a commission of up to 3.0% of the gross sales price per share sold and has agreed to provide Cantor with customary indemnification and contribution rights. Through September 14, 2015, the Company has issued 2,870,689 shares for net proceeds of \$3.8 million under the Sales Agreement.

On July 29, 2015, the Company entered into the Purchase Agreement with LPC, pursuant to which it has the right to sell, from time to time, to LPC up to \$45.0 million in shares of the Company's common stock through July 2017, subject to certain limitations and conditions set forth in the Purchase Agreement. During July 2015, LPC purchased \$5.0 million in shares of common stock. The Company received net proceeds of approximately \$4.8 million after expenses. Following the initial purchase, on any business day and as often as every other business day over the 24-month term of the Purchase Agreement, and up to an aggregate amount of an additional \$40.0 million (subject to certain limitations) of shares of Common Stock, the Company has the right, from time to time, at its sole discretion and subject to certain conditions to direct LPC to purchase up to 200,000 shares of Common Stock (not to exceed \$2.0 million in total purchase proceeds per purchase date). The purchase price of shares of Common Stock pursuant to the Purchase Agreement will be based on the prevailing market price at the time of sale as set forth in the Purchase Agreement. The Company will control the timing and amount of any sales of Common Stock to LPC. In addition, the Company may direct LPC to purchase additional amounts as accelerated purchases if on the date of a regular purchase the closing sale price of the Common Stock is not below the "threshold price" as set forth in the Purchase Agreement.

The Purchase Agreement contains customary representations, warranties and agreements of the Company and LPC, limitations and conditions to completing future sale transactions, indemnification rights and other obligations of the parties. There is no upper limit on the price per share that LPC could be obligated to pay for Common Stock under the Purchase Agreement. The Company has the right to terminate the Purchase Agreement upon one business days' notice, at no cost or penalty. Actual sales of shares of Common Stock to LPC under the Purchase Agreement will depend on a variety of factors to be determined by the Company from time to time, including (among others) market conditions, the trading price of the Common Stock and determinations by the Company as to other available and appropriate sources of funding for the Company. As consideration for entering into the Purchase Agreement, the Company issued to LPC 451,354 shares of Common Stock. The Company did not receive any cash proceeds from the issuance of these shares.

On September 2, 2015, the Company announced that it has engaged Morgan Stanley & Co. LLC to conduct a review of strategic alternatives to maximize shareholder value in response to third party initiated expressions of interest. Potential strategic alternatives to be explored and evaluated during the review process may include a possible sale of the Company, a strategic partnership with one or more parties or the licensing of some of the Company's proprietary technologies. The Company will not provide any commitment regarding when or if this strategic review process will result in any type of transaction and no assurance can be given that the Company will determine to pursue a potential sale, strategic partnership or licensing arrangement.

On September 14, 2015, the Company implemented a cost reduction and business realignment initiative pursuant to which the Company reduced its headcount by approximately 50 employees, or 17% of its workforce, and expects to significantly reduce its operating expenses in fiscal year 2016. In connection with this initiative, the Company expects to incur a charge of approximately \$0.4 million to operating expenses in the three month period ending September 30, 2015.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, performed an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, or the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K. As of June 30, 2015, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were effective insofar as they are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms, and they include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial and accounting officers and effected by our board of directors and management to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and board of directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of June 30, 2015. In making this assessment, our management used the criteria set forth by the framework in "Internal Control-Integrated Framework (1992)" issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on our assessment, our management believes that, as of June 30, 2015, our internal control over financial reporting is effective. In addition, no changes in our internal control over financial reporting have occurred during the three months ended June 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

KPMG LLP, the independent registered public accounting firm that audited our financial statements included elsewhere in this Annual Report on Form 10-K, has issued an attestation report on our internal control over financial reporting. That report appears in Item 8 of Part II of this Annual Report on Form 10-K and is incorporated by reference to this Item 9A.

Item 9B. Other Information

On September 10, 2015, we entered into a new employment agreement with Dennis P. Pyers, our Senior Vice President, Chief Accounting Officer and Controller. Mr. Pyers' previous employment agreement with us had expired.

Under the agreement, Mr. Pyers' base salary remains at \$300,000 per year subject to annual review by the compensation committee of our board of directors or, the Compensation Committee, and is eligible to participate in our incentive bonus plan in amounts and percentages as determined by the Compensation Committee, with a target cash bonus of 40% of his annual base salary. Mr. Pyers also is eligible to participate in our benefits programs (including equity incentive plans) as they may change from time to time. The term of the agreement extends until December 31, 2018 and is subject to annual renewals thereafter.

The agreement further provides that, if Mr. Pyers' employment is terminated by us without "cause" (as defined in the agreement and including a termination of employment due to our election not to renew the term of the agreement), then he will be entitled to: (a) continuation of base salary and group health benefits for a period of 12 months, (b) payment of an amount, payable in equal installments over a 12 month period, equal to the greater of the annual bonus paid to him for the preceding year or his target bonus for the year of termination, and (c) accelerated vesting of all outstanding equity awards. If Mr. Pyers' employment is terminated by us without cause (including a termination of employment due to our election not to renew the term of the agreement) upon or within 12 months following a "change in control" (as defined in the agreement), in lieu of the severance benefits described above, Mr. Pyers will be entitled to: (a) continuation of base salary and group health benefits for 18 months and (b) payment of a lump-sum amount equal to the greater of the annual bonus paid to him for the preceding year or his target bonus for the year of termination. In addition, upon the occurrence of a change in control, all outstanding equity awards held by Mr. Pyers will then become fully vested. All severance benefits payable under the agreement will be conditioned on Mr. Pyers' execution of a release of claims against us. The agreement also contains customary indemnification provisions and restrictive covenants.

The description of the agreement contained herein does not purport to be complete and is qualified in its entirety by reference to the complete text of the agreement, a copy of which is attached to this Annual Report on Form 10-K as Exhibit 10.44, and is incorporated herein by reference.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Directors and Corporate Governance

The information required by this Item 10 regarding directors and corporate governance is incorporated by reference to our definitive proxy statement for our 2015 Annual Meeting of Stockholders, or the 2015 Proxy Statement, under the headings “Proposal No. 1 – Election of Directors” and “Proposal No. 1 – Information on Our Board of Directors and Corporate Governance.”

Executive Officers

The information required by this Item 10 regarding executive officers is incorporated by reference to our 2015 Proxy Statement under the heading “Executive Officers.”

Compliance with Section 16(a) of the Exchange Act

The information concerning Compliance with Section 16(a) of the Exchange Act is incorporated by reference to our 2015 Proxy Statement under the heading “Section 16(a) Beneficial Ownership Reporting Compliance.”

Code of Ethics

The information concerning our Code of Business Conduct and Ethics is incorporated by reference to our 2015 Proxy Statement under the heading “Proposal No. 1– Information on Our Board of Directors and Corporate Governance – Meetings and Committees of the Board – Code of Business Conduct and Ethics.”

Item 11. Executive Compensation

The information required by this Item 11 is incorporated by reference to the 2015 Proxy Statement under the headings of “Executive Compensation” and “Director Compensation”.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Except as set forth below, the information required by Item 12 is incorporated by reference to the 2015 Proxy Statement under the heading “Security Ownership of Certain Beneficial Owners and Management,” and “Equity Compensation Plan Information.”

ASX-Required Disclosure

Corporations Act 2001 (Cth)

We are not subject to Chapters 6, 6A, 6B and 6C of the Corporations Act dealing with the acquisition of our shares (in particular, relating to substantial shareholdings and takeovers).

Under the Delaware General Corporation Law, we are generally permitted to purchase or redeem our outstanding shares out of funds legally available for that purpose without obtaining stockholder approval, provided that (i) our capital is not impaired; (ii) such purchase or redemption would not cause our capital to become impaired; (iii) the purchase price does not exceed the price at which the shares are redeemable at our option and (iv) immediately following any such redemption, we shall have outstanding one or more shares of one or more classes or series of stock, which shares shall have full voting powers. Our certificate of incorporation does not create any further limitation on our purchase or redemption of our shares.

Australian Disclosure Requirements

In addition to our primary listing on the NASDAQ Global Market, our shares of common stock are also quoted in the form CDIs on the Australian Securities Exchange (ASX) and trade under the symbol “UNS”. As part of our ASX listing, we are required to comply with various disclosure requirements as set out under the ASX Listing Rules. The following information is intended to comply with the ASX Listing Rules and is not intended to fulfill information required by this Annual Report on Form 10-K.

Substantial Shareholders

The information required herein is incorporated by reference to the 2015 Proxy Statement under the headings “Security Ownership of Certain Beneficial Owners and Management.”

Distribution of Common Stock and CDI Holders as of September 4, 2015

	CDIs	
	Number of Holders	Number of CDIs
1 — 1,000	1,367	684,002
1,001 — 5,000	2,205	6,353,545
5,001 — 10,000	1,098	8,794,602
10,001 — 100,000	2,644	89,063,228
100,001 — and over	521	179,003,827
	<u>7,835</u>	<u>283,899,204</u>

The number of stockholders holding less than a marketable parcel of shares of common stock was 1,539 based on the closing market price as of September 4, 2015.

There is no current on-market buy-back of our securities.

Twenty Largest CDI Holders as of September 4, 2015

Rank	Name	Number of CDIs Held	% of CDIs Outstanding
1.	Hertogs Investments Pty Limited	4,960,000	1.75
2.	Citicorp Nominees Pty Limited	4,810,277	1.69
3.	J & N Kaal Pty Limited <Kaal Super Fund A/C>	4,427,470	1.56
4.	Penila Investments Pty Ltd <Hornung Superannuation A/C>	4,325,870	1.52
5.	Admark Investments Pty Ltd <The Pinto Family A/C>	4,000,000	1.41
6.	Mr Bradley Gavin Downes	3,034,169	1.07
7.	Mr Dennis Banks + Mrs Janine Banks <Banks Super Fund A/C>	2,752,060	0.97
8.	Mrs Cherie Ann Lauder + Mr John William Lauder <J&C Lauder Family S/F A/C>	2,342,114	0.82
9.	Regnal Superannuation Pty Ltd <Regnal Super Fund No 2 A/C>	2,094,000	0.74
10.	Mr Michael Anthony Logan + Mrs Robyn Joy Logan <Marj Super Fund A/C>	1,712,000	0.60
11.	Mr Evan Philip Clucas + Ms Leanne Jane Weston <Kuranga Nursery Super A/C>	1,679,988	0.59
12.	Mr Warwick Wright	1,508,208	0.53
13.	Hertogs Family Superannuation Fund Pty Ltd <Hertogs Family S/Fund A/C>	1,500,000	0.53
14.	R J Services Pty Ltd <Super Fund A/C>	1,450,000	0.51
15.	Mr Alan Shortall	1,420,560	0.50
16.	UBS Nominees Pty Ltd	1,418,090	0.50
17.	National Nominees Limited	1,302,872	0.46
18.	Mr Joseph Zanca + Mrs Szerenke Zanca <Zanacorp Super Fund A/C>	1,255,000	0.44
19.	Mr Dennis John Banks + Mrs Janine Anne Banks <The Banks Super Fund A/C>	1,117,645	0.39
20.	Mr Victor John Plummer	1,100,000	0.39
Total		<u>48,210,323</u>	<u>16.98</u>

General Information

The name of our Secretary is Mr. John Ryan.

The complete mailing address, including zip code, of our principal executive offices is 250 Cross Farm Lane, York, Pennsylvania 17406.

The address of the principal registered office in Australia is 1 Chifley Square, Suite 3, Sydney NSW 2000 and our telephone number there is +61 2 8346 6500. The ASX Liaison Officer is Mr. Jeff Carter.

Registers of securities are held as follows:

- (a) For CDIs in Australia at Computershare Investor Services Pty Limited, Level 2, 45 St Georges Terrace Perth WA 6000 Australia, Investor Enquiries +61 8 9323 2000 (within Australia) +61 3 9415 4677 (outside Australia); and
- (b) For Common Stock in the United States at Computershare Investor Services, 250 Royall Street, Canton, MA 02021 USA, Tel: 800 662 7232.

Voting Rights

Unilife's by-laws provide that each stockholder has one vote for every share of common stock entitled to vote held of record by such stockholder and a proportionate vote for each fractional share of stock entitled to vote so held, unless otherwise provided by Delaware General Corporation Law or in the certificate of incorporation. Holders of restricted stock awards have the same voting rights as holders of shares of common stock.

If holders of CDIs wish to attend Unilife's general meetings, they will be able to do so. Under the ASX Listing Rules, Unilife, as an issuer of CDIs, must allow CDI holders to attend any meeting of the holders of the underlying securities unless relevant U.S. law at the time of the meeting prevents CDI holders from attending those meetings.

In order to vote at such meetings, CDI holders have the following options:

- (a) instructing CDN, as the legal owner, to vote the Unilife common stock underlying their CDIs in a particular manner. The instruction form must be completed and returned to Unilife's share registry prior to the meeting;
- (b) informing Unilife that they wish to nominate themselves or another person to be appointed as CDN's proxy for the purposes of attending and voting at the general meeting;
- (c) converting their CDIs into a holding of Unilife common stock prior to the record date for the meeting and voting these at the meeting (however, if thereafter the former CDI holder wishes to sell their investment on ASX, it would be necessary to convert Unilife common stock back to CDIs).

As holders of CDIs will not appear on Unilife's share register as the legal holders of Unilife common stock, they will not be entitled to vote at Unilife stockholder meetings unless one of the above steps is undertaken.

CDI Voting Instruction Forms and details of these alternatives will be included in each notice of meeting sent to CDI holders by Unilife.

Holders of options and phantom stock units are not entitled to vote.

Australian Corporate Governance Statement

The board of directors and employees of Unilife Corporation (“Unilife” or the “Company”) are committed to developing, promoting and maintaining a strong culture of good corporate governance and ethical conduct.

The board of directors confirms that our corporate governance framework is generally consistent with the Australian Securities Exchange’s (“ASX”) Corporate Governance Council’s “Corporate Governance Principles and Recommendations (3rd Edition)” (“ASX Governance Recommendations”), other than as set out below. To this end, we provide below a review of its governance framework using the same numbering as adopted for the principles as set out in the ASX Governance Recommendations.

This Corporate Governance Statement is current as of September 14, 2015 and has been approved by our board of directors.

Copies of our charters, codes and policies may be downloaded from the corporate governance section of our website (www.unilife.com).

We redomiciled to the United States in January 2010 and listed on The NASDAQ Global Market in February 2010. As a result and to meet the NASDAQ listing requirements, the policies and practices that we adopted are predominantly “US-focused”.

Principle 1 — Lay solid foundations for management and oversight

Recommendation 1.1 — Establish the functions reserved to the board and those delegated to senior executives and disclose those functions

The primary responsibility of:

- (a) the board of directors is to exercise their business judgment to act in what they reasonably believe to be in our best interests our stockholders’; and
- (b) the Chief Executive Officer is to oversee the day-to-day performance of Unilife (pursuant to powers delegated to the board of directors).

The board of directors’ responsibilities are recognized and documented on an aggregated basis by the Charter of the board of directors, which is available on the corporate governance section of our website.

While day-to-day management has been delegated to the Chief Executive Officer, it is noted that the following matters are specifically reserved for the attention of the board of directors:

- (a) providing input into and final approval of management’s development of corporate strategy and performance objectives;
- (b) reviewing, ratifying and monitoring systems of risk management and internal control, codes of conduct, and legal compliance;
- (c) ensuring appropriate resources are available to senior executives;
- (d) approving and monitoring the progress of major capital expenditure, capital management and acquisitions and divestments; and
- (e) approving and monitoring financial and other reporting.

Recommendation 1.2 — Disclose the process for submitting a director to shareholders as a candidate for election as a director and provide information regarding the director's candidacy.

The Nominating and Corporate Governance Committee is responsible for evaluating nominees for election as director, determining the criteria for selecting new directors, and selecting or recommending to the board director nominees. We undertake appropriate checks before appointing a person, or putting forward to stockholders a candidate for election as a director. Each year, we provide information to shareholders regarding director nominees to enable them to make an informed decision on whether or not to re-elect a director, including the director's relevant qualifications and experience and the skills they bring to the board of directors; details of any other material directorships currently held by the candidate, the term of office already served by the director, whether the director is considered to be independent, and a recommendation by the board of directors with respect to the re-election of the director. We will provide similar information regarding any candidate standing for election as a director for the first time.

Recommendation 1.3 — Enter into written agreements with directors and senior executives

We maintain employment agreements with each of our named executive officers. We are in the process of putting in place a letter of appointment for all of our non-executive directors. Director obligations are set forth in the Charter of the board of directors and in the Charters of each of the committees of our board of directors, all of which are available on the corporate governance section of our website.

Recommendation 1.4 — Accountability of company Secretary to the board through the chair, on all matters to do with the proper functioning of the board.

Our Secretary, Mr. John Ryan, is directly accountable to the board of directors through the Chairman of the board of directors for monitoring our compliance in respect of all corporate governance matters and compliance with all disclosure obligations. Each director is able to communicate directly with Mr. Ryan.

Recommendation 1.5 — Establish a policy concerning diversity and disclose it. The policy should include requirements for the board of directors to establish measurable objectives for achieving gender diversity and for the board of directors to assess annually both the objectives and progress in achieving them.

The board of directors has adopted a Diversity Policy which includes the responsibility to establish appropriate and measurable diversity objectives and for the board of directors to assess regularly the overall effectiveness of the objectives and annually review the progress in achieving the diversity objectives.

Unilife is committed to driving diversity across all levels of the Company. Diversity at Unilife signifies not only a blend of races, genders, ages, ethnicities, religions, cultural backgrounds, languages, social backgrounds and military service but also a range of experiences, perspectives, skill sets, capabilities and thought. We seek to hire the most qualified person for each position while also prioritizing diversity. At this time, given our significant hiring needs and desire to hire the most qualified individual, we have not established measurable objectives for achieving gender diversity.

As of May, 2015, women represented approximately 28% (74 of 266) of the total employee base, 17% (5 of 30) of the executive management and 17% (1 out of 6) of the board of directors.

Recommendation 1.6 — Disclose the process for evaluating the performance of the board of directors, its committees and individual directors

In accordance with the Nominating and Corporate Governance Committee Charter, the Nominating and Corporate Governance Committee periodically undertakes a formal review of the performance of the board of directors, its committees and individual directors.

A performance evaluation of the board of directors, its committees and individual directors was undertaken during fiscal year 2015 in accordance with the Nominating and Governance Committee Charter.

Recommendation 1.7 — Disclose the process for evaluating the performance of its senior executives

The Compensation Committee periodically undertakes a formal review of its senior executives against agreed goals and objectives.

A performance evaluation of senior executives was undertaken during fiscal year 2015.

Principle 2 — Structure the board of directors to add value

Recommendation 2.1 — The board of directors should establish a nomination committee

We have established a Nominating and Corporate Governance Committee which consists of three members, all of whom are independent directors (including the Chairman of the Nominating and Corporate Governance Committee). The members of the Nominating and Corporate Governance Committee are Mr. Galle (Chair), Mr. Lund and Ms. Wold. The Nominating and Corporate Governance Committee is governed by the Nominating and Corporate Governance Committee Charter. The Nominating and Corporate Governance Committee Charter includes the process and criteria for selecting new directors, a copy of which is available on the corporate governance section of the Company's website.

Recommendation 2.2 — Companies should have a board skills matrix

The Nominating and Corporate Governance Committee seeks to recruit and retain directors with a variety of skills and backgrounds, which may change as our Company grows and develops. The Nominating and Corporate Governance Committee has not established a board skills matrix, given that our company is changing rapidly and therefore our needs at the board of directors level are evolving. The process and considerations involved in appointing a director are included in our annual Proxy Statement under "Information on our Board of Directors and Corporate Governance" and the skills of our directors are set forth in our annual Proxy Statement under "Proposal No. 1 — Election of Directors." The Nominating and Corporate Governance Committee has considered and is satisfied that the composition of the Board reflects an appropriate range of skills and experience for Unilife to effectively discharge its responsibilities.

Recommendation 2.3 — Disclose the names of the directors considered by the board to be independent directors

Recommendation 2.4 — A majority of the board of directors should be independent directors

The Company considers that a director is an independent director where that director is free from any relationship that, in the opinion of the Board, would interfere with, or could be reasonably perceived to materially interfere with, the exercise of independent judgment in carrying out the responsibilities of a director, and otherwise meets the requirements of independence set forth in the rules of NASDAQ and the ASX, any regulatory agency (including the Securities and Exchange Commission) and any additional Board guidelines.

The board of directors is currently comprised of six directors. The six directors include five non-executive directors (including the Vice Chairman and Lead Independent Director) and one executive director (being the Chairman and Chief Executive Officer). Four of the five non-executive directors are considered "independent" in accordance with the NASDAQ listing rules and the ASX listing rules. These independent directors are Ms. Wold and Messrs. Lund, Galle and Hamill. Ms. Wold is the Vice Chairman of the board of directors and Lead Independent Director.

The length of service of each director on the Board is as follows:

Mr. Shortall (since 2002), Ms. Wold (since May 2010), Mr. Lund (since November 2009), Mr. Galle (since June 2008), Mr. Hamill (since August 2015) and Mr. Carter (since April 2006).

Recommendation 2.5 — The Chairman should be an independent director and the roles of Chairman and Chief Executive Officer should not be exercised by the same individual

The board of directors elects its Chairman of the board of directors and appoints the Chief Executive Officer according to its view of what is best for the Company at any given time. Mr. Alan Shortall is Chairman and CEO of the Company.

Mr. Shortall is not considered an independent director for ASX purposes because of his executive role with the Company. Mr. Shortall does not have any conflicts of interest with the Company and the Board is confident that Mr. Shortall is capable of exercising independent view and judgement in exercising his role as Chairman. Furthermore, the board of directors believes that the significant skills and experience gained in other businesses that Mr. Shortall brings to the role of Chairman outweigh any perceived lack of independence.

The board of directors does not believe there should be a fixed rule as to whether the offices of Chairman of the board of directors and the Chief Executive Officer should be vested in the same person or two different people, or whether the Chairman of the board of directors should be an employee of the Company or should be elected from among the non-employee directors. Our needs and the individuals available to serve in these roles may dictate different outcomes at different times, and the board of directors believes that retaining flexibility in these decisions is in our best interest and our stockholders'. Because the offices of Chairman of the board of directors and the Chief Executive Officer are vested in the same person, our board of directors has, in accordance with governance best practices, appointed a lead independent director.

Recommendation 2.6 — Disclosure of a program for director induction

The Nominating and Corporate Governance Committee Charter requires such committee to develop orientation materials for new directors and corporate governance-related continuing education for all directors. Indeed our board of directors does periodically receive continuing education to develop and maintain the skills and knowledge needed to perform their roles as directors effectively.

Furthermore, at our expense, the board of directors collectively or directors (acting as individuals) are entitled to seek advice from independent external advisers in relation to any matter which is considered necessary to fulfill their relevant duties and responsibilities. Individual directors seeking such advice must obtain the approval of the Chairman or the Lead Independent Director. Any advice so obtained will be made available to the board of directors.

Principle 3 — Act ethically and responsibly

Recommendation 3.1 — Establish a Code of Conduct and disclose it.

The Company has adopted a Code of Business Conduct and Ethics, as well as an Insider Trading Policy. Each of these has been prepared in accordance with Nasdaq rules and the ASX Governance Recommendations. They are both available on the corporate governance section of our website.

Principle 4 — Safeguard integrity in corporate reporting

Recommendation 4.1 — The board of directors should establish an Audit Committee. The Audit Committee should: (a) consist of non-executive directors only; (b) consist of a majority of independent directors; (c) be chaired by an independent chair who is not chair of the board of directors; and (d) have at least three members.

The Company has established an Audit Committee which consists of three members, all of whom are non-executive and independent directors (including the Chairman of the Audit Committee). The members of the Audit Committee are Mr. Lund (Chair), Ms. Wold, and Mr. Hamill. The Audit Committee is governed by the Audit Committee Charter, a copy of which is available on our website.

Information regarding the skills, experience and expertise of directors, including audit committee members in accordance with U.S. disclosure requirements, will be included in the 2015 Proxy Statement.

Recommendation 4.2 — The board should, before it approves the entity's financial statements for a financial period, receive from its CEO and CFO a declaration that, in their opinion, the financial records of the entity have been properly maintained and that the financial statements comply with the appropriate accounting standards and give a true and fair view of the financial position and performance of the entity and that the opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.

We refer shareholders to Item 9A of this Annual Report on Form 10-K. As stated above, Item 9A of this Annual Report on Form 10-K discloses information regarding the Company's controls and procedures, including management's evaluation of the effectiveness of our disclosure controls and procedures and management's evaluation of the effectiveness of our internal control over financial reporting. Furthermore, consistent with the Sarbanes-Oxley Act of 2002, our Chief Executive Officer and Chief Financial Officer provide certifications at the end of each Annual Report on Form-10K that we file. These certifications confirm the opinions of these executives that, among other things: the financial statements, and other financial information included in the report, fairly present in all material respects our financial condition, results of operations and cash flows as of, and for, the periods presented in the report.

Recommendation 4.3 — The external auditor should attend the annual general meeting of shareholders and be available to answer questions.

The Company's external auditor, KPMG, attends the Company's annual general meeting of shareholders and is available to answer questions from shareholders directly following that meeting.

Principle 5 — Make timely and balanced disclosure

Recommendation 5.1 — Establish a written policy for complying with continuous disclosure obligations under the ASX listing rules and disclose that policy

Unilife is committed to providing timely and balanced disclosure to the market and, in consequence, to meeting its continuous disclosure requirements. We established a Disclosure Committee for the purpose of ensuring significant matters requiring public disclosure are communicated to management and disclosed in a timely manner.

In accordance with its commitment to fully comply with its continuous disclosure requirements, we adopted a Continuous Disclosure Policy, together with other internal mechanisms and reporting requirements.

Principle 6 — Respect the rights of stockholders

Recommendation 6.1 — Provide information about the company and its governance to investors via its website

Recommendation 6.2 — Design and implement an investor relations program to facilitate effective two-way communication with investors

Recommendation 6.3 — Disclose the policies and processes in place to facilitate and encourage participation at meetings of stockholders

Recommendation 6.4 — Provide stockholders the option to receive communications from, and send communications to, the entity and its security registry electronically.

We communicate information, including our annual reports, SEC filings, investor call details, copies of our corporate governance charters, background information on directors and executive officers, board committee assignments, media releases, and product information and demonstrations, to stockholders through our website. We provide advanced notice of group briefings, including earning calls, stockholder meetings and investor events, and to the extent practicable, provide webcast links on our website. Key financial information and stock performance are also available on our website. Stockholders can raise questions to us by contacting us by telephone, facsimile, post or email, with relevant contact details being available on our website.

All stockholders are invited to attend our Annual Meeting of Stockholders, either in person or by proxy. The board of directors regards the Annual Meeting as an excellent forum in which to discuss issues relevant to the Company and thereby encourages full participation by stockholders. Stockholders have an opportunity to submit questions to the board of directors and our auditors. The meeting is also webcast to provide access to those stockholders who are unable to attend the Annual Meeting.

We seek to use multiple modes of communication, including electronic communication, to ensure that our communication with stockholders is frequent and done with ease. Stockholders (including holders of CHES Depositary Interests) may communicate with the board of directors electronically by submitting an email to john.ryan@unilife.com. All incoming communications are screened by our Company Secretary and transmitted to the intended recipient absent safety or security issues. Stockholders may also elect to receive email alerts from the Company by registering on our website and by following @unilife on Twitter.

Principle 7 — Recognize and manage risk

Recommendation 7.1 — (a) Establish a committee(s) to oversee risk which has at least three members, a majority of whom are independent directors, and is chaired by an independent director; and disclose the charter of the committee, the members of the committee, and the number of times the committee and the individual attendance of committee members; or (b) if there is no such committee, disclose the processes it employs for overseeing the entity's risk management framework.

We do not have a board committee that is tasked solely with overseeing Company risk. The board of directors is responsible for reviewing, ratifying and monitoring systems of risk management and internal control, codes of conduct, and legal compliance. In addition, the Audit Committee is responsible for (i) discussing guidelines and policies to govern the process by which risk assessment and management is undertaken and handled; and (ii) reviewing the effectiveness and adequacy of our internal control structure and considering with management, the internal auditors and the independent auditor whether any changes to the internal control structure are appropriate.

We have implemented an enterprise-risk management program, which is designed to ensure that risks including, amongst others, technology risks, economic risks, financial risks, regulatory risks and other operational risks are identified, evaluated and mitigated to enable the achievement of our goals.

Recommendation 7.2 — Review the company’s risk management framework at least annually so that it continues to be sound and disclose whether such a review has taken place.

Management provides the board of directors with frequent updates on the state of our business, including the risks that we face from time-to-time. These updates include up-to-date financial information, operational activity, clinical status and competitor updates. Management provides the board of directors with an annual review of management’s enterprise risk management assessment, which identifies particular events or circumstances relevant to our objectives (risks and opportunities), assessing them in terms of likelihood and magnitude of impact, determining a response strategy, and monitoring progress. These updates are founded on internal communications that are fostered internally through management meetings and other internal communications. These processes operate in addition to our Quality System, complaint handling processes, employee policies and standard operating procedures. The board of directors conducted its last annual review of management’s enterprise risk management assessment in May 2015.

As a U.S. public company, we are required to comply with the provisions of the Sarbanes-Oxley Act of 2002, which requires us to establish policies and internal controls over financial reporting to reduce certain risks to the business, including potential fraud. Our internal controls are audited annually by KPMG, its auditors, and by Protiviti, an independent consultant, to ensure compliance, and the results of their audits are reported to the audit committee. The Chief Executive Officer and Chief Financial Officer are required to evaluate the our internal controls on an annual basis and to certify to our auditors and the audit committee the following:

- All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting, which are reasonably likely to adversely affect our ability to record, process, summarize and report financial information; and
- Any fraud, whether or not material, that involves management or other employees who have a significant role in our internal control over financial reporting.

In addition, the board of directors holds regular meetings for the purposes of discussing and reviewing operational developments.

Recommendation 7.3 — Disclose if the Company has an internal audit function, how the function is structured and what role it performs. If the Company does not have an internal audit function, disclose that fact and the processes it employs for evaluating and continually improving the effectiveness of its risk management and internal control processes.

Due to our current size and business circumstances, we do not have an internal audit function. We will appoint an internal auditor if, and when, we consider this necessary.

As required under the Sarbanes-Oxley Act of 2002, we are required to evaluate and test our internal controls over financial reporting and we engage the services of an outside consultant to assist in carrying out these duties. As the outside consultant is independent of management, it provides for ongoing evaluation and opportunities to improve our risk management and internal processes.

In Item 9A of this Annual Report on Form 10-K, we have disclosed information regarding the Company’s Controls and Procedures, including management’s evaluation of the effectiveness of our disclosure controls and procedures and management’s evaluation of the effectiveness of our internal control over financial reporting.

Recommendation 7.4 — Disclose any material exposure to economic, environmental and social sustainability risks and, if it does, how it manages those risks.

We discuss material risks we face in Item 1A of this Annual Report on Form 10-K, including economic, environmental and social sustainability risks. We manage risk in accordance with the processes and procedures discussed in response to Recommendations 7.1 through 7.3.

Principle 8 — Remunerate fairly and responsibly

Recommendation 8.1 — Establish a Remuneration Committee

We have established a Compensation Committee to review and assess executive and director compensation. A copy of the Compensation Committee Charter is available on the corporate governance section of our website.

Our Compensation Committee consists of three members, all of whom are independent directors (including the Chairman of the Compensation Committee). The members of the Compensation Committee are Mr. Lund (Chair), Mr. Galle and Mr. Hamill.

Recommendation 8.2 — Disclose policies and practices of the company regarding the remuneration of non-executive and remuneration of executive directors and other senior executives.

Our Compensation Committee is responsible for making recommendations to the Board in relation to the Company's policies and practices regarding the remuneration of non-executive directors and the remuneration of executive directors and other senior executives, separately. Further details regarding the compensation policies and practices for executive and non-executive directors and other senior executives will be set out in our Annual Proxy statement. In accordance with the Compensation Committee Charter, no director is to be involved in the Compensation Committee meetings at which his or her remuneration is being discussed.

A copy of the Compensation Committee Charter is available on our website.

Recommendation 8.3 — Establish a policy on whether participants in an equity-based compensation plan are permitted to enter into transactions which limit the economic risk of participating in the plan and disclose that policy or summary of it.

Our Insider Trading Policy, which is available on the corporate governance section of our website, restricts participants in our Amended and Restated 2009 Stock Incentive Plan from entering into transactions which limit the economic risk of participating in such plan.

Additional ASX Required Disclosures

- (a) There were six board meetings and the audit, compensation, and nominating and corporate governance committees held 4, 5 and 2 meetings, respectively, during the reporting period. Director attendance at Board and Committee meetings is set out below.

	Meetings of the Board	Audit Committee	Compensation Committee	Nominating and Governance Committee
Alan Shortall	6	4*	5*	1*
Slavko James Joseph (Jim) Bosnjak	6	4	5	2
William Galle	6	3*	5	2
John Lund	6	4	5	2*
Mary Kate Wold	6	4	2*	2
Jeff Carter	6	1*	1*	2*

* Did not serve on the Committee during the reporting period.

- (b) *The names of Unilife's substantial holders, and the number of equity securities in which each substantial holder and their associates have a relevant interest, as disclosed in substantial holding notices given to Unilife. If a substantial holding notice discloses that related bodies corporate have the same relevant interest in the same number of equity securities, the annual report need only include the name of the holding company.*

The names of our substantial holders and their respective equity holdings are set forth in our annual Proxy Statement under "Security Ownership of Certain Beneficial Owners and Management."

- (c) *If during the reporting period any securities were purchased on-market: (i) under or for the purposes of an employee incentive plan; or (ii) to satisfy the entitlements of the holders of options or other rights to acquire securities granted under an employee incentive plan, then disclose (i) the total number of securities purchased during the reporting period and (ii) the average price per security at which the securities were purchased during the reporting period.*

We did not purchase any securities on market: (i) under or for the purposes of an employee incentive plan; or (ii) to satisfy the entitlements of the holders of options or other rights to acquire securities granted under an employee incentive plan.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item 13 is incorporated by reference to the 2015 Proxy Statement under the headings "– Information on Our Board of Directors and Corporate Governance" and "Certain Relationships and Related Party Transactions."

Item 14. Principal Accounting Fees and Services

The information required by this Item 14 is incorporated into this report by reference to the 2015 Proxy Statement under the heading "Proposal No. 2 – Ratification of Appointment of the Independent Registered Public Accounting Firm."

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this report:

(1) Financial Statements

The financial statements required by this Item 15 are set forth in Part II, Item 8 of this report.

(b) Exhibits. The following Exhibits are filed as a part of this report:

Exhibit No.	Description of Exhibit	Included Herewith	Incorporated by Reference Herein		
			Form	Exhibit	Filing Date
3.1	Certificate of Incorporation of Unilife Corporation		10	3.1	November 12, 2009
3.2	Amended and Restated Bylaws of Unilife Corporation		8-K	3.1	August 17, 2010
4.1	Form of Common Stock Certificate		10	4.1	November 12, 2009
4.2	Warrant to Purchase Common Stock dated April 17, 2013		10-K	4.4	September 13, 2013
4.3	Form of Indenture		S-3	4.4	June 30, 2014
10.1	Consultancy Agreement, dated as of January 22, 2009 between Unilife Medical Solutions Limited and Joblak Pty Ltd		10	10.15	November 12, 2009
10.2	Unilife Corporation 2009 Stock Incentive Plan, as amended on December 1, 2011		DEF 14A	Annex A	October 14, 2011
10.3	Unilife Medical Solutions Limited Exempt Employee Share Plan		10	10.19	November 12, 2009
10.4	Amended and Restated Operating Agreement dated December 14, 2009 of Unilife Cross Farm LLC		10/A	10.26	January 6, 2010
10.5	Form of Restricted Stock Agreement Under the Unilife Corporation 2009 Stock Incentive Plan		10-Q	10.1	March 24, 2010
10.6	Form of Unilife Corporation Nonstatutory Stock Option Notice		10-Q	10.2	March 24, 2010
10.7	Employment Agreement, dated as of July 27, 2010 between Unilife Corporation and Dennis P. Pyers		10-K	10.46	September 28, 2010
10.8	Loan Agreement between Metro Bank and Unilife Cross Farm LLC dated as of October 20, 2010		8-K	10.1	October 26, 2010
10.9	Term Note in the principal amount of \$14,250,000 dated as of October 20, 2010		8-K	10.2	October 26, 2010

Exhibit No.	Description of Exhibit	Included Herewith	Incorporated by Reference Herein		
			Form	Exhibit	Filing Date
10.10	Guaranty and Suretyship Agreement dated October 20, 2010 (Unilife Corporation)		8-K	10.4	October 26, 2010
10.11	Guaranty and Suretyship Agreement dated October 20, 2010 (Unilife Medical Solutions, Inc.)		8-K	10.5	October 26, 2010
10.12	Form of Warrant issued to Keystone Redevelopment Group, LLC and L2 Architecture on December 2, 2010		POS AM	10.58	December 10, 2010
10.13	Employment Agreement, effective October 1, 2011 between Unilife Corporation and Alan D. Shortall		10-Q	10.4	November 9, 2011
10.14	Employment Agreement, effective July 1, 2012 between Unilife Corporation and Ramin Mojdeh, Ph.D.		8-K	10.1	June 15, 2012
10.15	Letter Agreement, dated May 14, 2013, between Unilife Corporation and Ramin Mojdeh, Ph.D.		10-K	10.75	September 13, 2013
10.16	Amendment to Employment Agreement, effective September 12, 2013 between Unilife Corporation and Ramin Mojdeh, Ph.D.		10-K	10.76	September 13, 2013
10.17*	Credit Agreement, dated as of March 12, 2014, by and between Unilife Medical Solutions, Inc. and ROS Acquisition Offshore LP		10-Q/A	10.1	September 29, 2014
10.18	Royalty Agreement, dated as of March 12, 2014, by and between Royalty Opportunities S.A.R.L. and Unilife Medical Solutions, Inc.		10-Q/A	10.2	September 29, 2014
10.19	General Security Deed, dated as of March 12, 2014, by Unitract Syringe Pty Limited, Unilife Medical Solutions Limited and Unilife Corporation in favor of ROS Acquisition Offshore LP		10-Q	10.3	May 12, 2014
10.20	Omnibus Waiver and Amendment, dated as of March 12, 2014, by and among Unilife Cross Farm LLC, Unilife Medical Solutions, Inc., Unilife Corporation and Metro Bank		10-Q	10.4	May 12, 2014
10.21	Separation Agreement and General Release, dated March 18, 2014, by and between Unilife Corporation and R. Richard Wieland II		10-Q	10.5	May 12, 2014
10.22	Promissory Note, dated as of March 12, 2014, for up to \$60,000,000 by Unilife Medical Solutions, Inc. in favor of ROS Acquisition Offshore LP		10-Q	10.6	May 12, 2014

Exhibit No.	Description of Exhibit	Included Herewith	Incorporated by Reference Herein		
			Form	Exhibit	Filing Date
10.23	Guarantee, dated as of March 12, 2014, by Unilife Corporation, Unilife Cross Farms LLC, Unilife Medical Solutions Limited and Unitract Syringe Pty Limited in favor of ROS Acquisition Offshore LP and Royalty Opportunities S.A.R.L.		10-Q	10.7	May 12, 2014
10.24	Pledge and Security Agreement, dated as of March 12, 2014, by Unilife Medical Solutions, Inc., Unilife Cross Farms LLC, Unilife Medical Solutions Limited and Unitract Syringe Pty Limited in favor of ROS Acquisition Offshore LP		10-Q/A	10.3	September 29, 2014
10.25	Open-End Commercial Mortgage and Security Agreement, dated as of March 12, 2014, by and between Unilife Cross Farms LLC and ROS Acquisition Offshore LP, for itself and as agent for Royalty Opportunities S.A.R.L.		10-Q	10.9	May 12, 2014
10.26	Employment Agreement, dated September 15, 2014, between Unilife Corporation and John C. Ryan, Esq.		8-K	10.1	September 19, 2014
10.27	Amendment to Employment Agreement, dated September 15, 2014, between Unilife Corporation and Alan D. Shortall		8-K	10.2	September 19, 2014
10.28	Amendment to Employment Agreement, dated September 17, 2014, between Unilife Corporation and Alan D. Shortall		8-K	10.3	September 19, 2014
10.29	Amendment to Employment Agreement, dated September 15, 2014, between Unilife Corporation and Ramin Mojdeh, Ph.D.		8-K	10.4	September 19, 2014
10.30	Amendment to Employment Agreement, dated September 17, 2014, between Unilife Corporation and Ramin Mojdeh, Ph.D.		8-K	10.5	September 19, 2014
10.31	First Amendment to the Credit Agreement, dated September 30, 2014, between Unilife Medical Solutions, Inc. and ROS Acquisition Offshore LP		10-Q	10.1	November 12, 2014
10.32	First Amendment to the Royalty Agreement, dated September 30, 2014, between Unilife Medical Solutions, Inc. and Royalty Opportunities S.A.R.L.		10-Q	10.2	November 12, 2014
10.33	Employment Agreement, dated November 6, 2014, between Unilife Corporation and Mark V. Iampietro		10-Q	10.3	November 12, 2014
10.34	Employment Agreement, dated January 9, 2015, between Unilife Corporation and David C. Hastings		8-K	10.1	January 14, 2015
10.35	Amendment to Employment Agreement, dated January 9, 2015, between Unilife Corporation and Ramin Mojdeh, Ph.D.		8-K	10.3	January 14, 2015

Exhibit No.	Description of Exhibit	Included Herewith	Incorporated by Reference Herein		
			Form	Exhibit	Filing Date
10.36	Amendment to Employment Agreement, dated January 9, 2015, between Unilife Corporation and John C. Ryan		8-K	10.4	January 14, 2015
10.37	Form of Restricted Stock Agreement under the Unilife Corporation 2009 Stock Incentive Plan, dated November 14, 2014, between Unilife Corporation and Alan D. Shortall (4,000,000 shares of common stock)		S-8	4.2	November 14, 2014
10.38	Form of Restricted Stock Agreement under the Unilife Corporation Amended and Restated 2009 Stock Incentive Plan		10-Q	10.1	February 9, 2015
10.39	Form of Restricted Stock Units Notice under the Unilife Corporation Amended and Restated 2009 Stock Incentive Plan (US Directors)		10-Q	10.2	February 9, 2015
10.40	Form of Restricted Stock Agreement under the Unilife Corporation Amended and Restated 2009 Stock Incentive Plan (Australian Directors)		10-Q	10.3	February 9, 2015
10.41	Purchase Agreement, dated as of July 29, 2015, between Unilife Corporation and Lincoln Park Capital Fund, LLC		8-K (Film No. 151014075)	10.1	July 30, 2015
10.42	Controlled Equity Offering SM Sales Agreement, dated July 29, 2015, between Unilife Corporation and Cantor Fitzgerald & Co.		8-K (Film No. 151014081)	10.1	July 30, 2015
10.43	Second Amendment to the Credit Agreement, dated June 30, 2015, between Unilife Medical Solutions, Inc. and ROS Acquisition Offshore LP	X			
10.44	Employment Agreement, dated September 10, 2015 between Unilife Corporation and Dennis P. Pyers	X			
12.1	Statement regarding computation of Ratio of Earnings to Fixed Charges	X			
21	List of subsidiaries of Unilife Corporation	X			
23.1	Consent of KPMG LLP	X			
31.1	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer	X			
31.2	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer	X			
32.1	Section 1350 Certification	X			
32.2	Section 1350 Certification	X			

Exhibit No.	Description of Exhibit	Included Herewith	Incorporated by Reference Herein		
			Form	Exhibit	Filing Date
101.INS	XBRL Instance Document	X			
101.SCH	XBRL Taxonomy Extension Schema	X			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase	X			
101.LAB	XBRL Taxonomy Extension Label Linkbase	X			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase	X			
101.DEF	XBRL Taxonomy Extension Definition Linkbase	X			

* Confidential treatment has been requested for certain provisions of this Exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

UNILIFE CORPORATION

By: /s/ Alan Shortall

Name: Alan Shortall

Title: Chairman and Chief Executive Officer

Date: September 14, 2015

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Name	Title	Date
<u>/s/ Alan Shortall</u> Alan Shortall	Chairman and Chief Executive Officer (Principal Executive Officer)	September 14, 2015
<u>/s/ David C. Hastings</u> David C. Hastings	Senior Vice President and Chief Financial Officer (Principal Financial Officer)	September 14, 2015
<u>/s/ Dennis P. Pyers</u> Dennis P. Pyers	Senior Vice President and Controller (Principal Accounting Officer)	September 14, 2015
<u>/s/ Mary Katherine Wold</u> Mary Katherine Wold	Director	September 14, 2015
<u>/s/ John Lund</u> John Lund	Director	September 14, 2015
<u>/s/ Harry A. Hamill</u> Harry A. Hamill	Director	September 14, 2015
<u>/s/ Jeff Carter</u> Jeff Carter	Director	September 14, 2015
<u>/s/ William Galle</u> William Galle	Director	September 14, 2015

SECOND AMENDMENT TO CREDIT AGREEMENT

This SECOND AMENDMENT TO CREDIT AGREEMENT (this “Amendment”) is made and entered into as of June 30, 2015 by and among UNILIFE MEDICAL SOLUTIONS, INC., a Delaware corporation (the “Borrower”), the other Creditor Obligors party hereto and ROS ACQUISITION OFFSHORE LP, a Cayman Islands exempted limited partnership (the “Lender”).

WHEREAS, the Borrower and the Lender are party to that certain Credit Agreement, dated as of March 12, 2014 (as amended on September 30, 2014, and as further amended from time to time, the “Credit Agreement”), pursuant to which the Lender has extended credit to the Borrower on the terms set forth therein;

WHEREAS, the Borrower has requested that the Lender amend the Credit Agreement, as more fully described herein; and

WHEREAS, the Lender is willing to agree to such amendment, but only upon the terms and subject to the conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual agreements herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Definitions; Loan Document. Capitalized terms used herein without definition shall have the meanings assigned to such terms in the Credit Agreement. This Amendment shall constitute a Loan Document for all purposes of the Credit Agreement and the other Loan Documents. Each reference to “hereof”, “hereunder”, “herein” and “hereby” and each other similar reference and each reference to “this Agreement” and each other similar reference contained in the Credit Agreement shall, after this Amendment becomes effective, refer to the Credit Agreement as amended hereby.

2. Amendment. Section 8.4 of the Credit Agreement is hereby amended by deleting Section 8.4(c) in its entirety.

3. Conditions to Effectiveness of Amendment. This Amendment shall become effective upon receipt by (i) the Lender of a counterpart signature to this Amendment duly executed and delivered by the Borrower and each of the other Credit Obligors and (ii) the Credit Obligors of a counterpart signature to this Amendment duly executed and delivered by the Lender.

4. Expenses. The Borrower agrees to pay on demand all expenses of the Lender (including, without limitation, the fees and out-of-pocket expenses of Covington & Burling LLP, counsel to the Lender, and of local counsel, if any, who may be retained by or on behalf of the Lender) incurred in connection with the negotiation, preparation, execution and delivery of this Amendment and all other expenses of the Lender remaining unpaid as of the date hereof.

5. Representations and Warranties. The Credit Obligors represent and warrant to the Lender as follows:

(a) After giving effect to this Amendment, the representations and warranties of the Borrower and the Guarantors contained in the Credit Agreement or any other Loan Document shall, (i) with respect to representations and warranties that contain a materiality qualification, be true and correct in all respects on and as of the date hereof, and (ii) with respect to representations and warranties that do not contain a materiality qualification, be true and correct in all material respects on and as of the date hereof, and except that the representations and warranties limited by their terms to a specific date shall be true and correct as of such date.

(b) After giving effect to this Amendment, no Default or Event of Default has occurred or is continuing.

(c) (i) Each Credit Obligor has taken all necessary action to authorize the execution, delivery and performance of this Amendment; (ii) this Amendment has been duly executed and delivered by the Credit Obligors and constitutes each of the Credit Obligors' legal, valid and binding obligations, enforceable in accordance with its terms (except, in any case, as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization or similar laws affecting creditors' rights generally and by principles of equity), and (iii) no authorization or other action by, and no notice to or filing with, any Governmental Authority or other Person is required for the due execution, delivery or performance by any Credit Obligor of this Amendment.

6. No Implied Amendment or Waiver. Except as expressly set forth in this Amendment, this Amendment shall not, by implication or otherwise, limit, impair, constitute a waiver of or otherwise affect any rights or remedies of the Lender under the Credit Agreement or the other Loan Documents, or alter, modify, amend or in any way affect any of the terms, obligations or covenants contained in the Credit Agreement or the other Loan Documents, all of which shall continue in full force and effect. Nothing in this Amendment shall be construed to imply any willingness on the part of the Lender to agree to or grant any similar or future amendment, consent or waiver of any of the terms and conditions of the Credit Agreement or the other Loan Documents.

7. Reaffirmation of Security Interests. The Credit Obligors (i) affirm that each of the security interests and liens granted in or pursuant to the Loan Documents are valid and subsisting and (ii) agree that this Amendment shall in no manner impair or otherwise adversely affect any of the security interests and liens granted in or pursuant to the Loan Documents.

8. Reaffirmation of Guarantee. Each Guarantor (a) acknowledges and consents to all of the terms and conditions of this Amendment, (b) affirms all of its obligations under the Loan Documents and (c) agrees that this Amendment and all documents executed in connection herewith do not operate to reduce or discharge the Guarantor's obligations under the Loan Documents.

9. Waiver and Release. TO INDUCE THE LENDER TO AGREE TO THE TERMS OF THIS AMENDMENT, EACH CREDIT OBLIGOR REPRESENTS AND WARRANTS THAT AS OF THE DATE HEREOF THERE ARE NO CLAIMS OR OFFSETS AGAINST OR RIGHTS OF RECOUPMENT WITH RESPECT TO OR DEFENSES OR COUNTERCLAIMS TO ITS OBLIGATIONS UNDER THE LOAN DOCUMENTS AND IN ACCORDANCE THEREWITH IT:

(a) WAIVES ANY AND ALL SUCH CLAIMS, OFFSETS, RIGHTS OF RECOUPMENT, DEFENSES OR COUNTERCLAIMS, WHETHER KNOWN OR UNKNOWN, ARISING PRIOR TO THE DATE HEREOF; AND

(b) RELEASES AND DISCHARGES THE LENDER, ITS AFFILIATES AND ITS AND THEIR OFFICERS, DIRECTORS, EMPLOYEES, AGENTS, SHAREHOLDERS AND ATTORNEYS (COLLECTIVELY THE "RELEASED PARTIES") FROM ANY AND ALL OBLIGATIONS, INDEBTEDNESS, LIABILITIES, CLAIMS, RIGHTS, CAUSES OF ACTION OR DEMANDS WHATSOEVER, WHETHER KNOWN OR UNKNOWN, SUSPECTED OR UNSUSPECTED, IN LAW OR EQUITY, WHICH THE BORROWER EVER HAD, NOW HAS, CLAIMS TO HAVE OR MAY HAVE AGAINST ANY RELEASED PARTY ARISING PRIOR TO THE DATE HEREOF AND FROM OR IN CONNECTION WITH THE LOAN DOCUMENTS OR THE TRANSACTIONS CONTEMPLATED THEREBY.

10. Counterparts; Governing Law. This Amendment may be executed in any number of counterparts and by different parties hereto on separate counterparts, each of such when so executed and delivered shall be an original, but all of such counterparts shall together constitute but one and the same agreement. Delivery of an executed counterpart of a signature page of this Amendment by fax transmission or other electronic mail transmission (e.g., "pdf" or "tif") shall be effective as delivery of a manually executed counterpart of this Amendment. THIS AMENDMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (INCLUDING FOR SUCH PURPOSE SECTIONS 5-1401 AND 5-1402 OF THE GENERAL OBLIGATIONS LAW OF THE STATE OF NEW YORK).

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed by their respective officers thereunto duly authorized as of the day and year first above written.

UNILIFE MEDICAL SOLUTIONS, INC.

By: /s/ John C. Ryan
Name: John C. Ryan
Title: SVP, GC & Secretary

UNILIFE CORPORATION

By: /s/ John C. Ryan
Name: John C. Ryan
Title: SVP, GC & Secretary

UNILIFE CROSS FARM LLC

By: /s/ John C. Ryan
Name: John C. Ryan
Title: SVP, GC & Secretary

Executed by Unilife Medical Solutions Pty Limited in accordance with Section 127 of the *Corporations Act 2001*

/s/ Alan Shortall
Signature of director

Alan Shortall
Name of director (print)

Executed by Unitract Syringe Pty Ltd in accordance with Section 127 of the *Corporations Act 2001*

/s/ Alan Shortall
Signature of director

Alan Shortall
Name of director (print)

/s/ John C. Ryan
Signature of ~~director~~/company secretary
(Please delete as applicable)

John C. Ryan
Name of ~~director~~/company secretary (print)

/s/ John C. Ryan
Signature of ~~director~~/company secretary
(Please delete as applicable)

John C. Ryan
Name of ~~director~~/company secretary (print)

ROS ACQUISITION OFFSHORE, LP
as the Lender
By OrbiMed Advisors, LLC, its investment manager

By: /s/ Samuel D. Isaly
Name: Samuel D. Isaly
Title: Managing Member

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT is made and entered into as of this 10th day of September 2015, by and between Unilife Corporation (“Unilife”) and Dennis P. Pyers (“Pyers”). The term “Unilife” shall include its subsidiaries, affiliates, assigns and successors in interest under Sections 7, 8, and 13.

WHEREAS, Unilife is engaged in the business of designing, developing, manufacturing and supplying advanced drug delivery systems;

WHEREAS, Unilife desires to continue the employment of Pyers as Senior Vice President, Chief Accounting Officer and Controller under terms substantially similar to the terms of Pyers’ employment when he commenced employment at Unilife in 2010 and under terms substantially similar to other Executive Officers of Unilife; and

WHEREAS, Unilife and Pyers wish to enter into this employment agreement to set forth the terms of Pyers’ employment relationship with Unilife.

NOW, THEREFORE, in consideration of the promises and covenants set forth herein, and intending to be legally bound hereby, the parties agree as follows:

1. Term. This agreement shall be effective as of the date of this agreement and shall be for a multi-year term commencing on such effective date and expiring on December 31, 2018. This agreement will automatically renew for one-year periods annually thereafter, unless either party gives the other party thirty (30) days written notice in advance of the relevant expiration date of its intention not to renew the agreement. Upon expiration or earlier termination of this employment relationship, the parties will be relieved of their duties and obligations under this agreement, except that the rights and obligations of Unilife under Section 6 below shall remain in full force and effect until all appropriate payments have been made to Pyers and the rights and obligations of Pyers set forth in Sections 7 and 8 below shall remain in full force and effect and shall survive the expiration or termination of this agreement, regardless of the reason(s) for termination.

2. Position and Duties.

(a) Unilife will employ Pyers as Senior Vice President, Chief Accounting Officer and Controller and Pyers agrees to serve in such capacity for Unilife with responsibility for Unilife’s accounting and control functions and such other duties as are assigned to him by the Chief Financial Officer (“CFO”) of Unilife, and shall have vested in him the authority and duties typically held by an employee in such position. Pyers shall report to the Chief Financial Officer with respect to the performance of these duties and shall be a member of the Executive Team. In the performance of these duties, Pyers shall devote his knowledge, skill, attention, energies and all of his business time, and shall comply with all of Unilife’s policies, rules, and procedures, as they may be amended from time to time. Pyers shall not engage in any endeavor that would conflict with the rendition of his services to Unilife, either directly or indirectly, without the prior written consent of Unilife’s Chief Executive Officer (“CEO”); provided, however, Pyers may participate in civic, charitable, educational, industry and professional organizations, to the extent that such participation does not unreasonably interfere with the performance of his duties hereunder; and Pyers may also serve on corporate boards and committees, but only with the prior written consent of Unilife’s CEO.

(b) Notwithstanding the responsibilities and duties contained in Section 2(a) above, Pyers acknowledges that all material decisions relating to the management of Unilife’s business will be made by the CEO or the Board of Directors of Unilife. In addition, any decisions which have the capacity to affect significantly the financial standing of Unilife must be referred to the CFO, CEO or Board of Directors of Unilife who will have ultimate control in respect of these matters.

3. Compensation.

(a) Base Salary. Pyers shall be paid an annual base salary of Three Hundred Thousand Dollars (\$300,000) payable in accordance with Unilife's standard payroll practices. Pyers' base salary will be subject to the customary withholding and employment taxes, as required by law, with respect to compensation paid by an employer to an employee. At the discretion of the Compensation Committee of the Board of Directors of Unilife (the "Compensation Committee"), Pyers shall be eligible for increases in base salary. Further, Unilife will not reduce Pyers' base salary to less than what is agreed to herein.

(b) Bonus. Pyers shall be eligible to participate in Unilife's Incentive Bonus Plan in amounts and percentages as determined by Unilife's Compensation Committee. The target cash bonus amount for such bonus will be forty percent (40%) of base salary. Bonuses are subject to achievement of such goals and objectives as the Compensation Committee determines in a set of Key Performance Indicators. Any bonus payable for a fiscal or calendar year shall be paid in a lump-sum payment no later than the date that is two and one-half months after the close of the relevant fiscal or calendar year. Pyers' bonuses will be subject to the customary withholding and employment taxes, as required by law, with respect to compensation paid by an employer to an employee.

4. Benefits.

(a) Benefits Generally Available to Unilife Employees. Pyers shall be eligible to participate in Unilife's benefits programs (including any equity incentive plan of Unilife or its affiliates), as they may change from time to time. The benefits provided to Pyers will be the same as the benefits provided to other similarly situated Unilife employees, and may be changed upon expiration or other termination of the current benefits contracts. For further information, Pyers should review any applicable benefit plan documents, which will govern the terms of the benefits.

(b) Vacation. Pyers shall also receive four (4) weeks of paid vacation per calendar year. Any unused vacation days may be carried over or paid in lieu thereof, to the extent allowed by Unilife's policy for similarly situated employees or at the CEO's discretion.

(c) Equity Plans. Any stock options and other stock-based awards that Pyers may receive from Unilife shall be governed by the applicable, underlying award agreement and the terms of the 2009 Stock Incentive Plan or any successor plan under which the award is granted.

(d) Expenses. Unilife shall reimburse Pyers for all reasonable and necessary expenses incurred by him in carrying out his duties under this agreement in accordance with

Unilife's business expense policies, including without limitation, requirements with respect to reporting, documentation and payment of such expenses. All such expenses shall be paid promptly after submission in accordance with Unilife's policies, but no later than December 31st of the calendar year following the year in which such expenses were incurred.

5. Indemnification. Unilife agrees to provide Pyers with indemnification equivalent to that provided to other members of senior management and insurance coverage pursuant to Unilife's Directors and Officers insurance policies, as amended from time to time.

6. Termination and Pay upon Termination.

(a) General Rule. In the event that Unilife terminates this agreement and Pyers' employment without Cause as defined herein, including employment termination due to Unilife's election not to renew this agreement where Pyers was willing and able to continue performing services under the terms of this agreement, Unilife will pay Pyers the severance benefits provided in subparagraphs (i) through (iv) of this Section 6(a).

(i) his base salary, at the rate in effect immediately before the date that Pyers' employment terminates, for twelve (12) months, in accordance with Unilife's standard payroll practices then in effect, commencing on the fifteenth (15th) day after the date that Pyers' employment terminates and the General Release provided for in Section 9 of this Agreement becomes irrevocable;

(ii) provided that Pyers is eligible for and timely elects to receive COBRA health, vision and dental care continuation coverage, the cost of Pyers' COBRA health, vision and dental care continuation coverage premiums (for himself and his eligible dependents) for twelve (12) months, commencing on the first of the month immediately after the month which includes the date that Pyers' employment terminates and the General Release provided for in Section 9 of this agreement becomes irrevocable;

(iii) payment of an amount, equal to the greater of the amount of the bonus, if any, earned by and paid to Pyers for the last completed bonus year prior to the year in which his employment terminates or the target bonus for which Pyers was eligible to earn in the bonus year in which his employment is terminated, which will be payable in equal installments over a twelve (12) month period, in accordance with Unilife's standard payroll practices then in effect, commencing on the fifteenth (15th) day after the date that Pyers' employment terminates and the General Release provided for in Section 9 of this Agreement becomes irrevocable; and

(iv) notwithstanding anything to the contrary, all of Pyers' outstanding and unvested options and other stock-based awards shall vest immediately upon such termination of employment without Cause.

In the event that Pyers terminates this agreement for any reason, including Pyers' election not to renew the agreement, Pyers shall not receive any compensation or benefits from the time that he ceases to devote full time and attention to Unilife's business, except such compensation as was earned prior to that date, including, but not limited to unused vacation and vested equity grants. In addition, Pyers agrees to provide Unilife with thirty (30) days advance written notice of his intent to terminate his employment, whether during the initial term or any renewal thereof. Upon termination of this agreement, the parties will be relieved of their duties and obligations,

except that the rights and obligations of Unilife under this Section 6(a) shall remain in full force and effect until all appropriate payments have been made to Pyers, if applicable, and the rights and obligations of Pyers set forth in Sections 7 and 8 below shall remain in full force and effect and shall survive the expiration or termination of this agreement, regardless of the reason(s) for termination. Upon termination of this agreement, Pyers shall not have any further contact with any customers of Unilife on behalf of a competing entity until the expiration of the conditions of Section 8 of this agreement.

(b) Termination Following a Change in Control.

(i) Termination Pay. Notwithstanding paragraph (a) immediately above, in the event that Unilife terminates this agreement and Pyers' employment without Cause as defined herein, including employment termination due to Unilife's election not to renew this agreement where Pyers was willing and able to continue performing services under the terms of this agreement, in either case coincident with or within twelve months after a Change in Control as defined in subparagraph (iii) immediately below, then Unilife, in lieu of and not in duplication of the severance compensation provided for in paragraph (a) immediately above, shall pay Pyers:

(A) his base salary, at the rate in effect immediately before the date that Pyers' employment terminates, for eighteen (18) months, in accordance with Unilife's standard payroll practices then in effect, commencing on the fifteenth (15th) day after the date that Pyers' employment terminates and the General Release provided for in Section 9 of this Agreement becomes irrevocable,

(B) provided that Pyers is eligible for and timely elects to receive COBRA health, vision and dental care continuation coverage, the cost of Pyers' COBRA health, vision and dental care continuation coverage premiums (for himself and his eligible dependents) for eighteen (18) months, commencing on with the first of the month immediately after the month which includes the date that Pyers' employment terminates and the General Release provided for in Section 9 of this Agreement becomes irrevocable,

(C) payment of a lump-sum amount, equal to the greater of the amount of the bonus, if any, earned by and paid to Pyers for the last completed bonus year prior to the year in which his employment terminates or the target bonus for which Pyers was eligible to earn in the bonus year in which his employment is terminated, which will be payable on the fifteenth (15th) day after the date that Pyers' employment terminates and the General Release provided for in Section 9 of this Agreement becomes irrevocable, and

(D) notwithstanding anything to the contrary, all of Pyers' outstanding and unvested options and other stock-based awards shall vest immediately upon a Change in Control.

(ii) Definition of "Cause". "Cause" will mean any one or more of the following:

(A) material neglect of assigned duties, willful misconduct in connection with the performance of duties, or refusal to perform assigned duties

(other than by reason of disability) which continues uncured for thirty (30) days following receipt of written notice of such deficiency from the CEO, specifying the scope and nature of the deficiency;

(B) engaging in any act of dishonesty, any act of moral turpitude, any illegal conduct or committing a crime that causes material harm to Unilife or its reputation;

(C) being barred from working in a Food and Drug Administration (“FDA”) regulated industry by the FDA or otherwise being sanctioned by the FDA or any similar international body;

(D) breaching, in any material respect, the terms of any agreement with Unilife; or

(E) commencement of employment with any other employer while an employee of Unilife without the prior written consent of the CEO.

Any determination of “Cause” as used herein will be made in good faith by the CEO.

(iii) Definition of “Change in Control”. “Change in Control” means a: (i) Change in Ownership of Unilife Corporation, (ii) Change in Effective Control of Unilife Corporation, or a (iii) Change in the Ownership of Assets of Unilife Corporation, all as described herein and construed in accordance with section 409A of the Internal Revenue Code of 1986, as amended (the “Code”).

(A) A Change in Ownership of Unilife Corporation shall occur on the date that any one Person acquires, or Persons Acting as a Group (or Group) acquire, ownership of the capital stock of Unilife Corporation that, together with the stock held by such Person or Group, constitutes more than fifty percent (50%) of the total fair market value or total voting power of the capital stock of Unilife Corporation. However, if any one Person is, or Persons Acting as a Group are, considered to own more than fifty percent (50%) of the total fair market value or total voting power of the capital stock of Unilife Corporation, the acquisition of additional stock by the same Person or Persons Acting as a Group is not considered to cause a Change in Ownership of Unilife Corporation or to cause a Change in Effective Control of Unilife Corporation. An increase in the percentage of capital stock owned by any one Person, or Persons Acting as a Group, as a result of a transaction in which Unilife Corporation acquires its stock in exchange for property will be treated as an acquisition of stock.

(B) A Change in Effective Control of Unilife Corporation shall occur on the date a majority of members of the Board of Directors of Unilife Corporation is replaced during any twelve (12)-month period by directors whose appointment or election is not endorsed by a majority of the members of the Board of Directors of Unilife Corporation before the date of the appointment or election.

(C) A Change in the Ownership of Assets of Unilife Corporation shall occur on the date that any one Person acquires, or Persons Acting as a Group acquire (or has or have acquired during the twelve (12)-month period ending on

the date of the most recent acquisition by such Person or Persons), assets (including tangible/real property and intangible property (such as goodwill)) from Unilife Corporation the total gross fair market value of which is more than fifty percent (50%) of the total gross fair market value of all of the assets of Unilife Corporation immediately before such acquisition or acquisitions. For this purpose, gross fair market value means the value of the assets of Unilife Corporation, or the value of the assets being disposed of, determined without regard to any liabilities associated with such assets.

(D) The following rules of construction apply in interpreting the definition of Change in Control:

(I) A Person means any individual, entity or group within the meaning of Section 13(d) (3) or 14(d) (2) of the Securities Exchange Act of 1934, as amended, other than employee benefit plans sponsored or maintained by Unilife Corporation and by entities controlled by Unilife Corporation or an underwriter of the capital stock of Unilife Corporation in a registered public offering.

(II) Persons will be considered to be Persons Acting as a Group if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with the corporation. If a Person owns stock in both corporations that enter into a merger, consolidation, purchase or acquisition of stock, or similar transaction, such shareholder is considered to be acting as a Group with other shareholders only with respect to the ownership in that corporation before the transaction giving rise to the change and not with respect to the ownership interest in the other corporation. Persons will not be considered to be acting as a Group solely because they purchase assets of the same corporation at the same time or purchase or own stock of the same corporation at the same time, or as a result of the same public offering.

(III) For purposes of this Section 6(b), fair market value shall be determined in accordance with Code Section 409A.

(IV) A Change in Control shall not include a transfer to a related person as described in Code section 409A or a public offering of capital stock of Unilife Corporation.

(E) For purposes of this Section 6(b), Code section 318(a) applies to determine stock ownership. Stock underlying a vested option is considered owned by the individual who holds the vested option (and the stock underlying an unvested option is not considered owned by the individual who holds the unvested option). For purposes of the preceding sentence, however, if a vested option is exercisable for stock that is not substantially vested (as defined by Treasury Regulation §1.83-3(b) and (j)), the stock underlying the option is not treated as owned by the individual who holds the option.

7. Confidential Information.

(a) Pyers acknowledges that Unilife has a valuable property interest in all aspects of its business relationships with its customers, clients, vendors and suppliers. In the course of Pyers' work with Unilife, Pyers will become aware of and familiar with secret and confidential information of Unilife relating to its customers, clients, vendors and suppliers, and its internal business operations. Secret and confidential information includes, but is not limited to, Unilife's business plans, customer lists, customer data, marketing plans, supplier and vendor lists and cost information, software and computer programs, data processing systems and information contained therein, financial statements, financial data, acquisition and divestiture plans, and any other trade secrets or confidential or proprietary information, documents, reports, plans, or data, of or about Unilife that is not already available to the public or was known to Pyers prior to his employment with Unilife.

(b) Pyers agrees that he will not, without the written consent of Unilife, during the term of this agreement or thereafter, disclose or make any use of secret and confidential information, except as may be required in the performance of his duties under Section 2 of this agreement. Pyers agrees that, following the termination of his employment with Unilife for any reason, he will never use secret and confidential information to compete with Unilife in any manner, and he will never disclose any secret and confidential information to any other business or individual, unless such secret or confidential information is: (i) publicly known through no breach of the provisions of this Section 7 by either party, (ii) lawfully disclosed by a third party, or (iii) disclosed pursuant to legal requirement or court order. In no event shall any disclosure made to investment banking firms or private equity firms at the request of Unilife and as part of Pyers' duties ever be considered a violation of this Section 7.

(c) Upon termination of this agreement, Pyers shall surrender to Unilife all records and all paper and/or electronic copies made of those records that pertain to any aspect of the business of Unilife, including all secret and confidential information.

8. Agreement Not To Compete.

(a) In consideration for employment by Unilife and the benefits of this agreement, Pyers agrees to be bound by the covenant not to compete as set forth in Section 8 of this agreement below; provided however, this non-compete covenant will extend for a period of two (2) years post-employment, if Pyers resigns his employment with Unilife or if Unilife terminates Pyers' employment for Cause, and provided further that this non-compete covenant will extend for a period of one (1) year post-employment if Pyers' employment with Unilife is terminated by Unilife for any reason, other than Cause.

(b) Pyers agrees that during the term of his employment he will not, directly or indirectly:

(i) render services to, become employed by, be engaged as a consultant by, own, or have a financial or other interest in (either as an individual, partner, joint venture, owner, manager, employee, partner, officer, director, independent contractor, or other similar role) any business that is engaged in any business activity that is in direct competition with the activities of Unilife, as of the date of the termination of this agreement.

(ii) induce, offer, assist, encourage, or suggest that another business or enterprise offer employment to or enter into a consulting arrangement with any individual who is employed by Unilife, or induce, offer, assist, encourage, or suggest that any Unilife employee terminate his or her employment with Unilife, or accept employment with any other business or enterprise.

(c) In the event that Pyers commits any breach of Section 8(b) above, Pyers acknowledges that Unilife would suffer substantial and irreparable harm and damages. Accordingly, Pyers hereby agrees that in such event, Unilife shall be entitled to temporary and/or permanent injunctive relief, without the necessity of proving damage, to enforce the provisions of this Section, all without prejudice to any and all other remedies that Unilife may have at law or in equity and that Unilife may elect or invoke. Pyers agrees that if any of the provisions of this Section are or become unenforceable, the remainder hereof shall nevertheless remain binding upon him to the fullest extent possible, taking into consideration the purposes and spirit of this agreement. Any invalid or unenforceable provision is to be reformed to the maximum time, geographic and/or business limitations permitted by applicable laws, so as to be valid and enforceable.

(d) Pyers expressly acknowledges and agrees that the restrictive covenants set forth in Sections 7 and 8 above are absolutely necessary to protect the legitimate business interests of Unilife, because he is employed in a position of trust and confidence and is provided with extensive access to Unilife's most confidential and proprietary trade secrets, and has significant involvement in important business relationships, which constitute the goodwill of Unilife. Pyers further agrees and acknowledges that these restrictive covenants are reasonable, will not restrict him from earning a livelihood following the termination of employment, and are intended by the parties to be enforceable following termination of employment for any reason.

(e) In the event that Unilife must bring legal action to enforce or seek a remedy for any breach of the provisions of Sections 7 or 8 of this agreement and Pyers is found by a court to have breached any of these provisions, Pyers agrees to reimburse Unilife for any and all expenses, including attorneys' fees and court costs, incurred by it in enforcing the terms of these Sections of the agreement.

9. General Release. As a condition of receiving the severance compensation and benefits described in Section 6, Unilife and Pyers will execute a mutual general release of claims (which is in a form acceptable to Unilife); provided that, to the extent that any claim that Unilife may have against Pyers would not be covered under the D&O insurance of Unilife, then Unilife would not release such claim under the mutual release. Such general release would not include rights to previously vested options or claims for any compensation or benefits earned (including, without limitation, unused vacation), or reimbursement of expenses incurred, through the date of termination. Such release must be agreed to, executed and irrevocable no later than 30 days following Pyers' termination date.

10. Dispute Resolution. Any controversy, claim or dispute involving the parties (or their affiliated persons) directly or indirectly concerning this agreement shall be finally settled by binding arbitration held in Montgomery County, Pennsylvania by one arbitrator (who is mutually acceptable to both parties as well as licensed to practice law in the Commonwealth of Pennsylvania) in accordance with the rules of employment arbitration then followed by the American Arbitration Association or any successor to the functions thereof. The arbitrator shall apply Pennsylvania law in the resolution of all controversies, claims and disputes and shall have

the right and authority to determine how his or her decision or determination as to each issue or matter in dispute may be implemented or enforced. Any decision or award of the arbitrator shall be final and conclusive for both Pyers and Unilife (and its affiliates), and there shall be no appeal there from other than causes of appeal allowed by the Federal Arbitration Act. Unilife shall bear all costs of the arbitrator in any action brought under this agreement. The arbitrator shall have the power to award attorney's fees and arbitration costs to the prevailing party, if the award of attorney's fees and litigation costs would be permitted by a court. The parties hereto agree that any action to compel arbitration may be brought in the appropriate Pennsylvania state or federal court, and in connection with such action to compel, the laws of the Commonwealth of Pennsylvania and the Federal Arbitration Act shall control. Application may also be made to such court for confirmation of any decision or award of the arbitrator, for an order of the enforcement and for any other remedies, which may be necessary to effectuate such decision or award. The parties hereto hereby consent to the jurisdiction of the arbitrator and of such court and waive any objection to the jurisdiction of such arbitrator and court.

11. Non-waiver. A waiver of any provision of this agreement by either party shall not prevent either party from enforcing that provision or any other provision hereof.

12. Assignment. This agreement is personal and may not be assigned by Pyers. Any assignment of this agreement between Unilife (or its successor) and its affiliates (and their successors) shall not constitute a termination of Pyers' employment hereunder. This agreement (including the Restrictive Covenants set forth in Sections 7 and 8) shall inure to the benefit of and be binding upon any successor to Unilife. The parties specifically understand and agree that the non-compete provisions of Section 8 will inure to the benefit of a successor and that Pyers will remain bound by these provisions in the event of a sale or corporate reorganization of Unilife.

13. Severability. Each provision of this agreement is severable and distinct from, and independent of, every other provision hereof. If one provision hereof is declared void, the remaining provisions shall remain in effect. Any provision of this agreement which is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective only to the extent of such prohibition or unenforceability without invalidating or affecting the remaining provisions hereof, and any such prohibition or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction.

14. Entire Agreement. This agreement contains the entire agreement of the parties concerning the employment relationship and supersedes any prior agreements or understandings between the parties concerning the terms and conditions of Pyers' employment, whether oral or written; provided, however, that Pyers' equity grants shall be governed by the equity grant documents; provided further, that any stock options or other stock-based awards provided to Pyers shall be governed by Unilife's stock incentive plans as they are amended from time to time, except as provided herein. The parties acknowledge, in entering into this agreement that they have not relied upon any promise or inducement not specifically set forth herein. Any changes to this agreement must be in writing and signed by both parties.

15. Section 409A.

(a) This agreement is intended to comply with, or otherwise be exempt from, Code section 409A and any regulations and Treasury guidance promulgated thereunder, and Unilife shall be required to interpret the terms of this agreement as necessary to comply with the requirements of Code section 409A.

(b) Unilife shall undertake to administer, interpret, and construe this agreement in a manner that does not result in the imposition on Pyers of any additional tax, penalty, or interest under Code section 409A.

(c) Unilife and Pyers agree that they will execute any and all amendments to this agreement permitted under applicable law as they mutually agree in good faith may be necessary to ensure compliance with the distribution provisions of Code section 409A or as otherwise needed to ensure that this agreement complies with that section.

(d) The preceding provisions, however, shall not be construed as a guarantee by Unilife of any particular tax effect to Pyers under this agreement. Unilife shall not be liable to Pyers for any payment made under this agreement that is determined to result in an additional tax, penalty, or interest under Code section 409A, nor for reporting in good faith any payment made under this agreement as an amount includible in gross income under that section.

(e) For purposes of Code section 409A, the right to a series of installment payments under this agreement shall be treated as a right to a series of separate payments.

(f) With respect to any reimbursement of future expenses of, or any provision of in-kind benefits to, Pyers, as specified under this agreement, such reimbursement of expenses or provision of in-kind benefits shall be subject to the following conditions: (i) the expenses eligible for reimbursement or the amount of in-kind benefits provided in one taxable year shall not affect the expenses eligible for reimbursement or the amount of in-kind benefits provided in any other taxable year, except for any medical reimbursement arrangement providing for the reimbursement of expenses referred to in Code section 105(b); (ii) the reimbursement of an eligible expense shall be made no later than the end of the year after the year in which such expense was incurred; and (iii) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit. Any tax gross-up payment shall be made by no later than the end of the calendar year following the year in which Pyers remits the taxes.

(g) "Termination of employment," "resignation," or words of similar import, as used in this agreement means, for purposes of any payments under this agreement that are payments of deferred compensation subject to Code section 409A, Pyers' "separation from service" as defined in that section.

(h) If a payment obligation under this agreement arises on account of Pyers' separation from service while Pyers is a "specified employee" (as defined under Code section 409A and determined in good faith by the Unilife), any payment of "deferred compensation" (as defined under Treasury regulation section 1.409A-1(b)(1), after giving effect to the exemptions in Treasury regulation sections 1.409A-1(b)(3) through (b)(12)) that is scheduled to be paid within six (6) months after such separation from service shall accrue without interest and shall be paid within 15 days after the end of the six-month period beginning on the date of such separation from service or, if earlier, within 15 days after the appointment of the personal representative or executor of Pyers' estate following his death.

(i) To the extent that under the terms of the agreement the execution of a general release of claims is a condition to Pyers receiving severance or other benefits under the

agreement, the Company will provide Pyers with the form of release agreement within seven days after Pyers' separation from service. To be entitled to the severance or other benefits, Pyers must execute and deliver to the Company the release agreement on or before the last day of the minimum required waiver consideration period provided under the Age Discrimination in Employment Act or other applicable law or such other date as may be specified in the release agreement. If Pyers timely delivers an executed release agreement to the Company, and Pyers does not revoke the release agreement during the minimum revocation period required under applicable law, if any, the severance or other benefits shall be paid or commence being paid, as applicable, on or after the date on which the release agreement becomes effective as specified in the agreement. If, however, the period during which Pyers has discretion to execute or revoke the release agreement straddles two calendar years, no such payment shall be made or benefit provided earlier than the first day of the second such calendar year, regardless of within which calendar year Pyers actually delivers the executed release agreement to the Company. Consistent with Section 409A, Pyers may not, directly or indirectly, designate the calendar year of payment.

16. Excise Tax on Parachute Payments. Pyers shall bear all expense of, and be solely responsible for, all federal, state, local or foreign taxes due with respect to any payment received hereunder, including, without limitation, any excise tax imposed by Code section 4999. Notwithstanding the foregoing, if any payment or distribution by Unilife to or for the benefit of Pyers, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise pursuant to or by reason of any other agreement, policy, plan, program or arrangement or the lapse or termination of any restriction on or the vesting or exercisability of any payment or benefit, would be subject to the excise tax imposed by Section 4999 of the Code (or any successor provision thereto) or to any similar tax imposed by state or local law (such tax or taxes are hereafter collectively referred to as the "Excise Tax"), then the aggregate amount of such payments and benefits (each such payment or benefit, a "Payment") payable to Pyers shall be reduced to the aggregate amount of Payments that may be made to Pyers without incurring an Excise Tax in accordance with the immediately following sentence; provided that such reduction shall only be imposed if the net after-tax benefit of the Payments retained by Pyers (after giving effect to such reduction) is equal to or greater than the net after-tax benefit (after giving effect to the Excise Tax) of the Payments to Pyers without any such reduction. If the Firm (as defined below) determines that a reduction is required by this Section 16, then such reduction shall be made in the following order: (i) first, any future cash payments (if any) shall be reduced (if necessary, to zero); (ii) second, any current cash payments shall be reduced (if necessary, to zero); (iii) third, all non-cash payments (other than equity or equity derivative related payments) shall be reduced (if necessary, to zero); and (iv) fourth, all equity or equity derivative payments shall be reduced.

For purposes of this Section 16, "net after-tax benefit" shall mean (i) the total of all Payments which Pyers receives or is then entitled to receive from Unilife, less (ii) the amount of all federal, state, local and foreign income taxes payable with respect to such Payment calculated at the maximum marginal income tax rate for each year in which the foregoing shall be paid to Pyers (based on the rate in effect for such year as set forth in the Code or other applicable tax law as in effect at the time of the first payment of the foregoing), less (iii) the amount of the applicable Excise Tax, if any, imposed with respect to the Payment.

The foregoing determination shall be made by a nationally recognized human resources consulting or accounting firm (the "Firm") selected by Unilife and reasonably acceptable to Pyers (which may be, but will not be required to be, Unilife's independent auditors). The Firm

shall submit its determination and detailed supporting calculations to both Pyers and Unilife within fifteen (15) days after receipt of a notice from either Unilife or Pyers that Pyers may receive Payments. If the Firm determines that none of the Total Payments, after taking into account any reduction required by this Section 16, constitutes a “parachute payment” within the meaning of Code section 280G, it will, at the same time as it makes such determination, furnish Pyers and Unilife an opinion that Pyers has substantial authority not to report any excise tax under Code section 4999 on his federal income tax return.

Pyers and Unilife shall each provide the Firm access to and copies of any books, records, and documents in the possession of Pyers or Unilife, as the case may be, reasonably requested by the Firm, and otherwise cooperate with the Firm in connection with the preparation and issuance of the determinations and calculations contemplated by this Section 16. The fees and expenses of the Firm for its services in connection with the determinations and calculations contemplated by this Section 16 shall be borne by Unilife.

17. Counterparts. This agreement may be executed on separate counterparts, each of which is deemed to be an original and all of which taken together constitute one and the same agreement.

18. Interpretation. The captions and headings of this agreement are not part of the provisions hereof and shall have no force or effect.

19. Notices. Any notices, requests, demands and other communications provided for by this agreement shall be sufficient if in writing and if hand delivered, sent by overnight courier, or sent by registered or certified mail to Pyers at the last address he has filed in writing with Unilife or, in the case of Unilife, to Unilife’s CEO at Unilife’s principal executive offices.

20. Governing Law. The terms of this agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Pennsylvania without giving effect to provisions thereof regarding conflict of laws.

21. Representations and Warranties. Pyers represents and warrants to Unilife that he is not bound by any restrictive covenants and has no prior or other obligations or commitments of any kind that would in any way prevent, restrict, hinder or interfere with Pyers’ acceptance of employment or the performance of all duties and services hereunder to the fullest extent of Pyers’ ability and knowledge, except for the duty of confidentiality owed to former employers. If Pyers has misrepresented the representation and warranty provided herein, then Pyers would be liable to Unilife for all damages incurred as a consequence thereof, including attorney’s fees and costs of court.

[Remainder of the page left blank]

IN WITNESS WHEREOF, and wishing to be legally bound, the parties have executed this agreement as of the date first above written.

UNILIFE CORPORATION:

Dennis P. Pyers:

By: /s/ Alan D. Shortall
Alan D. Shortall
Chief Executive Officer

/s/ Dennis P. Pyers

Exhibit 12.1

**Calculation of Ratio of Earnings to Fixed Charges
(In thousands)**

Fixed Charges:

	2015	2014	Fiscal Year Ended June 30,		2011
			2013	2012	
Interest expense	\$ 6,368	\$ 7,332	\$ 2,392	\$ 2,120	\$ 511
Capitalized interest	2,161	—	—	—	323
Estimate of interest within rental expense	<u>295</u>	<u>193</u>	<u>108</u>	<u>84</u>	<u>217</u>
Fixed Charges	<u>\$ 8,824</u>	<u>\$ 7,525</u>	<u>\$ 2,500</u>	<u>\$ 2,204</u>	<u>\$ 1,051</u>

Earnings:

Add:

Loss before income taxes	\$(90,849)	\$(57,899)	\$(63,198)	\$(52,302)	\$(40,682)
Fixed charges	8,824	7,525	2,500	2,204	1,051

Less:

Capitalized interest	<u>(2,161)</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>(323)</u>
Deficiency of earnings to cover fixed charges	<u>\$(84,186)</u>	<u>\$(50,374)</u>	<u>\$(60,698)</u>	<u>\$(50,098)</u>	<u>\$(39,954)</u>

Ratio of earnings to fixed charges¹

— — — — —

¹ Earnings for the fiscal years ended June 30, 2015, 2014, 2013, 2012, and 2011 were inadequate to cover fixed charges and accordingly, no ratio to fixed charges is disclosed for those periods.

Entity	Jurisdiction of Formation
Unilife Medical Solutions, Inc.	Delaware
Unilife Cross Farm, LLC	Delaware
Unitract Syringe Pty Limited	Australia
Unilife Medical Solutions Limited	Australia

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors
Unilife Corporation:

We consent to the incorporation by reference on Form S-8 (Registration Statement Nos. 333-200223, 333-193358, 333-186049, 333-178882 and 333-164964) and on Form S-3 (Registration Statement Nos. 333-197122 and 333-173195) of Unilife Corporation of our reports dated September 14, 2015, with respect to the consolidated balance sheets of Unilife Corporation and subsidiaries as of June 30, 2015 and 2014, and the related consolidated statements of operations and comprehensive loss, stockholders' (deficit) equity, and cash flows for each of the fiscal years in the three-year period ended June 30, 2015, and the effectiveness of internal control over financial reporting as of June 30, 2015, which reports appear in the June 30, 2015 annual report on Form 10-K of Unilife Corporation.

Our report on the consolidated financial statements dated September 14, 2015 contains an explanatory paragraph that states that the Company has incurred recurring losses from operations and has limited cash resources, which raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

/s/ KPMG LLP

Harrisburg, Pennsylvania
September 14, 2015

Certification of Chief Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Alan Shortall, certify that:

1. I have reviewed this Annual Report on Form 10-K of Unilife Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Alan Shortall

Name: Alan Shortall

Title: Chairman and Chief Executive Officer

Date: September 14, 2015

Certification of Chief Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, David C. Hastings, certify that:

1. I have reviewed this Annual Report on Form 10-K of Unilife Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ David C. Hastings

Name: David C. Hastings

Title: Chief Financial Officer

Date: September 14, 2015

**Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Annual Report of Unilife Corporation (the “Company”) on Form 10-K for the fiscal year ended June 30, 2015 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Alan Shortall, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Alan Shortall

Name: Alan Shortall

Title: Chairman and Chief Executive Officer

Date: September 14, 2015

**Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Annual Report of Unilife Corporation (the “Company”) on Form 10-K for the fiscal year ended June 30, 2015 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, David C. Hastings, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ David C. Hastings

Name: David C. Hastings

Title: Chief Financial Officer

Date: September 14, 2015