UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): **June 2, 2014**

Aastrom Biosciences, Inc.
(Exact name of registrant as specified in its charter)

Michigan	**000-22025**	**94-3096597**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

24 Frank Lloyd Wright Drive, Lobby K, Ann Arbor, Michigan	**48105**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(734) 418-4400**

Not Applicable
Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01. Entry into a Material Definitive Agreement

In connection with the closing of the purchase of the CTRM Business (see Item 2.01 below), Aastrom Biosciences, Inc., or the Company, a Michigan corporation, entered into the following agreements:

Transition Services Agreement

On the Closing Date, the Company and Genzyme Corporation (Genzyme), a subsidiary of the Seller (as defined below), entered into a Transition Services Agreement (the TSA). Pursuant to the TSA, Seller and the Selling Persons (as defined below) will provide certain transition services to the Company related to the operation of the CTRM Business, including specified general administrative and information technology services for up to twelve (12) months following the Closing Date. The fees payable by the Company for each service provided under the TSA are based on the rates generally charged by Seller to Seller's affiliates for such services. The TSA also provides for certain indemnification obligations related to certain breaches of obligations by either party and other specified matters under the TSA.

Transition Supply Agreement

On the Closing Date, the Company and Genzyme entered into a Transition Supply Agreement, (the Supply Agreement) providing for the manufacturing and supply of certain raw materials on behalf of the Company. Pursuant to the Supply Agreement, Seller will make available to the Company, as from the Closing Date, on a transitional basis the specified raw materials to the same extent they were available to the CTRM Business prior to the Closing Date. The term of the Supply Agreement is twelve (12) months and is subject to termination upon various events set forth in the Supply Agreement, including termination at the Company's option upon prior written notice.

The foregoing descriptions of the TSA and Supply Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of the TSA and the Supply Agreement, copies of which are attached hereto as Exhibits 10.1 and 10.2, respectively.

Item 2.01. Completion of Acquisition or Disposition of Assets

On May 30, 2014 (the Closing Date), the Company completed its acquisition of certain assets, including all of the outstanding equity interests of Genzyme Biosurgery ApS, a wholly-owned subsidiary of Sanofi, a French société anonyme (Seller or Sanofi), and over 250 patents and patent applications of Seller and certain of its subsidiaries (together with the Seller, the Selling Persons) and assumed certain liabilities of the Selling Persons for purposes of acquiring the

portions of the cell therapy and regenerative medicine business of the Selling Persons (the CTRM Business), which researches, develops, manufactures, markets and sells the Carticel®, MACI™ and Epicel® products, also referred to as the acquired products, or the CTRM products, (the Transaction). Pursuant to the terms of the Asset Purchase Agreement (the Asset Purchase Agreement), by and between the Company and Sanofi, in consideration for the sale of the CTRM Business, the Company paid a total purchase price of approximately $6.5 million, as follows: (a) $4 million was paid in cash on the Closing Date, and (b) $2.5 million will be paid in accordance with a promissory note in principal amount of $2.5 million with interest accruing at the short term applicable federal rate in effect on the Closing Date (the Promissory Note), prepayable without prepayment penalty, and due upon the earliest to occur of (i) July 30, 2014, (ii) a liquidation, dissolution or winding up of the Company, or a (iii) sale of the Company.

Concurrent with the closing of the Transaction, the Company and Seller entered into (i) certain IP assignment and license agreements to effect the transfer and license of the intellectual property related to the CTRM Business being assigned and/or licensed to the Company, (ii) certain assignment and assumption of lease agreements for each of the real property leases being assigned to the Company, and (iii) the agreements described above under Item 1.01.

A copy of the Asset Purchase Agreement is attached to the Company's Current Report on Form 8-K filed on April 23, 2014, as Exhibit 2.1 and the Promissory Note is Exhibit 4.3.7 thereto, and is incorporated herein by

reference. We encourage you to read the Purchase Agreement for a more complete understanding of the Transaction. The foregoing descriptions of the Asset Purchase Agreement, the Promissory Note and the Transaction do not purport to be complete and are qualified in their entirety by reference to the full text of the Asset Purchase Agreement and the Promissory Note.

CTRM BUSINESS

Acquisition of Sanofi's Cell Therapy and Regenerative Medicine (CTRM) Business

We believe that Sanofi's Cell Therapy and Regenerative Medicine (CTRM) business has been a pioneer in the development and commercialization of autologous cell therapies. The CTRM portfolio includes three marketed autologous cell therapy products: Carticel® (autologous cultured chondrocytes), a first-generation product for autologous chondrocyte implantation (ACI), MACI™ (matrix-applied characterized autologous cultured chondrocytes), a third-generation ACI product, and Epicel® (cultured epidermal autografts), a permanent skin replacement for full thickness burns greater than or equal to 30% of total body surface area.

Cartilage Defects

Damage to cartilage in the knee can occur from acute trauma or repetitive trauma from playing sports, exercising, working or performing everyday activities. When damaged, cartilage in the knee does not heal on its own. If left untreated, cartilage defects can progress and lead to degenerative joint disease, osteoarthritis and total knee replacement, a poor option for younger and more active patients.

For patients diagnosed with cartilage defects, there are several treatment options, including arthroscopic debridement/chondroplasty, marrow stimulation techniques such as microfracture, osteochondral autografts for smaller cartilage injuries, allografts, and autologous chondrocyte implants for larger, more complex injuries.

Carticel

Carticel, a first-generation ACI product for the treatment and repair of cartilage defects in the knee, is the first and only U.S. Food and Drug Administration (FDA) approved autologous cartilage repair product. Carticel is indicated for the repair of symptomatic cartilage defects of the femoral condyle (medial, lateral or trochlea) caused by acute or repetitive trauma, in patients who have had an inadequate response to a prior arthroscopic or other surgical repair procedure such as debridement, microfracture, drilling/abrasion arthroplasty, or osteochondral allograft/autograft. Carticel received a Biologics License Application (BLA) approval in 1997 and currently is marketed in the United States. Over 20,000 patients have been treated to date with Carticel in the United States.

Carticel is implanted by orthopedic surgeons after obtaining a cartilage biopsy during an initial arthroscopic procedure. The patient's chondrocytes, which are the cells that produce cartilage, are isolated and expanded in a current Good Manufacturing Practices (cGMP) manufacturing process. During a second surgical procedure, the cells are implanted in the cartilage defect under a sutured periosteal flap, where they produce new hyaline cartilage. The therapeutic advantage of this approach relative to other approaches, such as microfracture, is that the autologous chondrocytes produce the hyaline cartilage that is naturally present in the knee, rather than fibrous cartilage which lacks durability and the wear characteristics of hyaline cartilage.

The Study of the Treatment of Articular Repair (STAR) was designed to determine the safety and efficacy of Carticel in patients who had an inadequate response to a prior cartilage repair procedure. Completed in 2005, this FDA post-approval commitment was a four-year, prospective, multicenter study of 154 patients at 29 participating sites. In a clinically challenging population comprised of patients who suffered moderate-to-large chondral defects and who failed at least one prior surgical cartilage repair treatment, Carticel demonstrated long-term durability up to four years and statistically significant and clinically meaningful reductions in pain and improvement in function. Efficacy data demonstrating durability of repair are now out to 20 years for Carticel.

U.S. Competitive Environment

The main competitor for Carticel in the U.S. is the microfracture procedure. Microfracture is a minimally invasive procedure that can be performed during the initial arthroscopic procedure. Short term results are generally considered good in smaller cartilage defects. Other competitive treatments in the U.S. include autograft/allograft procedures and a juvenile donor-derived allograft product DeNovo NT from Zimmer, Inc.

Carticel is the only FDA-approved ACI product on the market in the United States. We are aware of one ACI product in development. Histogenics Corporation began a phase 3 study of its Neocart implant in February 2010. Neocart is an autologous chondrocyte tissue implant under development for

treatment of symptomatic articular cartilage lesions on the femur.

MACI

MACI™ (matrix-applied characterized autologous cultured chondrocytes), is a third-generation ACI product for the treatment of focal chondral cartilage defects in the knee. MACI has been commercially available in the European Union (EU) since 1998. MACI received Marketing Authorization in Europe in July 2013 by meeting the requirements of the Advanced Therapy and Medicinal Product (ATMP) guidelines. MACI is the first and only tissue engineered ATMP product approved by the European Commission. Over 9,500 patients have been treated with MACI outside the United States since 1998.

Similar to Carticel, during an initial surgical procedure, a surgeon obtains a biopsy of healthy cartilage and the chondrocytes are isolated, expanded and uniformly seeded onto a bioabsorbable Type I/IIIa collagen membrane to form the implant in a cGMP manufacturing process at a facility in Copenhagen, Denmark. During a second surgical procedure, the implant is trimmed to the size of the defect and fixed in the defect with fibrin glue.

The advantage of MACI relative to Carticel is that it provides the same efficacy with improvement in ease of use for the physician and reduced morbidity for the patient. The implant procedure for MACI is less invasive than for Carticel, entailing a mini-arthrotomy or even arthroscopic delivery, eliminating the need for a periosteum harvest and sutures.

The pivotal clinical trial supporting MACI registration in Europe, Superiority of MACI Implant to Microfracture Treatment (SUMMIT), was completed in 2012. Analysis of this 144 patient superiority study demonstrated that there is a statistically significant and clinically meaningful improvement in the co-primary endpoint of pain and function for those patients treated with MACI implant compared to microfracture. We expect that the FDA may require an additional clinical trial to support approval of a BLA in the United States.

Competitive Environment

The competitive treatment alternatives to MACI in the EU are the same as those for Carticel in the U.S., including debridement/chondroplasty, microfracture, and osteochondral autografts. Although there is very little use of allografts or allograft-derived products, the competitive product environment is much more robust. Competitors include microfracture augmentation products such as ChondroGide® from Geistlich Biomaterials and direct ACI competitors including ChondroCelect® from Tigenix

Epicel

Epicel® (cultured epidermal autografts) is a permanent skin replacement for full thickness burns greater than or equal to 30% of total body surface area. Epicel is the only FDA-approved autologous epidermal product available for large total surface area burns. Epicel was approved in the United States as a Humanitarian Use Device, or HUD, in 2007, and is supplied outside the U.S. on a named-patient basis. Approximately 100 patients are treated with Epicel in the U.S. each year. As a HUD, Epicel cannot be sold for an amount that exceeds the costs of research and development, fabrication, and distribution.

Epicel is produced by isolating and expanding keratinocytes, which are the predominant cell type in the epidermis or outer layer of the skin, obtained from a biopsy of a patient's healthy skin. Epicel is an important treatment option

for patients with severe burns because these patients need a keratinocyte-based epithelium and there is very little skin, which is the only other source of keratinocyte-based epithelium, available for autografts for these patients.

Competitive Environment

Patients suffering catastrophic burns over a significant portion of total body surface area have few options for permanent skin coverage. When undamaged skin is available, a procedure known as meshed split-thickness auto-grafting can be considered. However, this option becomes less viable as the percentage of total body surface area burn increases.

Sales and Marketing

The U.S. Carticel commercial organization is comprised of approximately 30 employees, including Clinical Account Executives, Regional Sales Directors and a Government Accounts Manager. Sales of Epicel are supported by a Clinical Account Executive and Medical Science Liasons. Sales of MACI outside the U.S. are supported by a team of three employees in the United Kingdom and Greece.

Reimbursement coverage for Carticel is widespread. The 15 largest payers, representing approximately 98% of commercial lives, have a formal medical policy that allows treatment with Carticel within labeled indications. These 15 plans represent approximately 132 million covered lives and include the top five national plans — WellPoint, United Healthcare, Aetna, CIGNA and Humana.

US Bioservices Corporation (USB) is the exclusive distributor of Carticel in the United States. USB purchases and takes title to Carticel upon shipment of the product. USB works with the payers on behalf of patients and surgeons to ensure medical coverage and to obtain reimbursement for Carticel implantation procedures. Aastrom retains all responsibility for shipment of the product to the surgical suite and may have certain indemnification obligations to USB. USB would also be the exclusive distributor of MACI in the United States, if and when it is approved by the FDA.

Manufacturing

Aastrom has acquired two cell manufacturing facilities as part of the CTRM business in Cambridge, Massachusetts and Copenhagen, Denmark. The Cambridge facility, which is approved by the FDA, is used for U.S. manufacturing and distribution of Carticel, Epicel manufacturing and worldwide distribution and also manufactured MACI for the SUMMIT study conducted for approval in Europe. The Cambridge facility also houses the Manufacturing and Technical Services organization, which is responsible for process development, release assay development, and technology transfers between sites and departments. The Copenhagen manufacturing facility, which is approved by the Danish Medicines Agency (DKMA), is responsible for MACI manufacturing and distribution in Europe.

Intellectual Property

Aastrom has acquired a multinational intellectual property estate relating to the CTRM business. The intellectual property estate includes patents and patent applications directed to chondrocyte implants and related technologies. Although we do not own any patents or patent applications relating to Epicel, we do own issued patents directed to the combinations of chondrocytes and collagen membranes used in Carticel and MACI, which are scheduled to expire in August of 2016 in the U.S. and in August of 2017 abroad. In certain foreign countries, selected patent rights covering Carticel are scheduled to expire in 2022.

We also own a broadly filed trademark portfolio with registrations for Carticel, MACI, and Epicel.

Interests of Certain Persons in the Acquisition

Transferred Employees

Pursuant to the terms of the Asset Purchase Agreement, Aastrom has agreed to provide to each U.S. employee of Sanofi who accepts an offer of employment with Aastrom a position with similar duties and responsibilities, an annual base salary that is not reduced by more than 10% of the salary provided by Sanofi, target cash incentive compensation and certain other employee benefits that are generally comparable in the aggregate to those provided by Sanofi. In addition, Aastrom agreed to accept a transfer agreement with each Greek and U.K. employee of Sanofi so that each employee transfer to Aastrom became effective as of the Closing Date.

RISK FACTORS

Set forth below are certain risk factors relating to the Transaction and the CTRM business acquired by Aastrom. These are not the only risks of the Transaction and the CTRM business, but represent the risks that we believe to be material. The risk factors relating to the CTRM business will apply to the combined company going forward because a substantial portion of the business of the combined company will now consist of the CTRM business. Before investing in Aastrom's securities, you should also carefully consider the risk factors associated with Aastrom's historic business, including those set forth under the caption "Risk Factors" in Aastrom's Annual Report on Form 10-K for the fiscal year ended December 31, 2013, as filed with the SEC on March 13, 2014, and the risk factors and other information contained in Aastrom's other filings with the SEC from time to time. Unless the context requires otherwise, "we", "us", "our" and "Aastrom" refer to Aastrom Biosciences, Inc.

Risks Related to our Acquisition of the CTRM Business

The failure to successfully integrate the CTRM business and operations in the expected time frame may adversely affect the combined company's future results.

We believe that the acquisition of the CTRM business will result in certain benefits, including certain manufacturing, sales and distribution and operational efficiencies. However, to realize these anticipated benefits, Aastrom's existing business and the CTRM business must be successfully combined. We may be unable to effectively integrate the CTRM business into our organization, make the CTRM business profitable, and may not succeed in managing the acquired business or the larger company that results from this acquisition. The process of integration of an acquired business may subject us to a number of risks, including:

- failure to successfully manage relationships with clients, distributors and suppliers;
- demands on management related to the increase in size of the Company after the acquisition;
- diversion of management attention;
- potential difficulties integrating and harmonizing financial reporting systems;
- difficulties in the assimilation and retention of employees;
- inability to retain the management, key personnel and other employees of the CTRM business;
- inability to establish uniform standards, controls, systems, procedures and policies;
- inability to retain the customers of the CTRM business;
- exposure to legal claims for activities of the CTRM business prior to acquisition; and
- incurrence of additional expenses in connection with the integration process.

If the CTRM business is not successfully integrated into our Company, our business, financial condition and results of operations could be materially adversely affected, as well as our professional reputation. Furthermore, if

we are unable to successfully integrate the CTRM business and operations, or if there are delays in combining the businesses, the anticipated benefits of the acquisition may not be realized fully or at all or may take longer to realize than expected. Successful integration of the CTRM business will depend on our ability to manage these operations, to realize opportunities for revenue growth presented by our acquired products and eliminate certain excess costs of the CTRM business.

Our due diligence may not have revealed all material issues that may be present in the CTRM business.

Although we conducted due diligence on the CTRM business, we cannot assure you that this diligence revealed all material issues that may be present in the CTRM business, that it would be possible to uncover all material issues through a customary amount of due diligence, or that factors outside of Aastrom's or the Seller's control will not later arise. As a result, we may be forced to later incur additional expense, write-down or write-off assets, restructure the operations of the CTRM business, or incur impairment or other charges that could result in losses. In addition, unexpected risks may arise and previously known risks may materialize in a manner not consistent with our preliminary risk analysis.

We will incur significant acquisition-related integration costs in connection with the acquisition.

We have developed a plan to integrate the operations of the CTRM business with our existing business. In connection with that plan, we anticipate that we will incur certain non-recurring charges in connection with this integration; however, we cannot identify the timing, nature and amount of all such charges as of the date of this report. Further, we incurred significant transaction costs relating to negotiating and completing the acquisition. These integration costs and transaction expenses will be charged as an expense in the period incurred. The significant transaction costs and acquisition-related integration costs could materially affect our results of operations in the period in which such charges are recorded.

Successful operation of the CTRM business is not assured, and we may be unable to successfully achieve profitability of the CTRM business. Additionally, actual results relating to the CTRM business may differ from any guidance issued by us concerning future cash expenditures and growth of the CTRM business or the anticipated impact of the acquisition on the operating results of the combined company, and these differences could be material. The CTRM business may not break even following the acquisition.

The CTRM business has been operating at a loss in recent periods. Although we intend to take steps to manage the CTRM business more efficiently, including streamlining certain processes and implementing lean manufacturing practices, we cannot provide any assurance that the CTRM business will be able to operate profitably or that such activities will be successful.

Further, we cannot provide assurances with respect to the future cash expenditures or growth rates we may realize as a result of our acquisition of the CTRM business. Although we expect the CTRM business to achieve profitability, the CTRM business has experienced substantial quarter-to-quarter variations in levels of demand and we expect that these variances may continue in the future. The CTRM business also has experienced flat to declining sales growth and these trends may continue in the future. Additional risks and uncertainties that could cause actual results to differ materially from currently anticipated results include, but are not limited to, risks relating to our ability to successfully integrate the CTRM business; our ability to continue to commercialize the acquired products; market acceptance of the acquired products; our ability to successfully launch new products and applications in the target markets of the CTRM business; competition; our sales, marketing and distribution capabilities; our planned sales, marketing, and research and development activities; reduction in manufacturing spending or changes in budget priorities by customers; interruptions or delays in the supply of components or materials for, or manufacturing of, the acquired products, which in certain cases are purchased through sole and single source suppliers; unanticipated increases in costs or expenses; risks associated with international operations; and other risks. Our actual financial condition and results of operations following the acquisition of the CTRM business may not be consistent with, or evident from, the guidance we provide. Other unknown or unpredictable factors could also harm our results. Consequently, actual results or developments anticipated by us may not be realized or, even if substantially realized, may not have the expected consequences to, or effects on, us. Any failure to meet such guidance could have a material adverse effect on the trading price or volume of our stock.

The CTRM business and the commercial and financial success of our acquisition of the CTRM business depend, in part, on the commercial success of the acquired products: Epicel, Carticel and MACI.

The CTRM business' success, and consequently the success of our acquisition of the CTRM business, depends on the continued success of the commercialization of its products, Epicel and Carticel (which we refer to as our U.S. approved products), each of which have been approved by the FDA, and MACI (which we refer to collectively with our U.S. approved products as our acquired products), which was centrally approved by the European Medicines Agency (EMA).

Our ability to maintain and increase revenues from sales of these products following our acquisition of the CTRM business will depend on several factors, including:

- our ability to increase market demand for these products through our own marketing and sales activities, and any other arrangements to promote these products that we may later establish;
- our ability to maintain and defend the patent protection and regulatory exclusivity of these products;
- our ability to continue to manufacture these products in sufficient quantities and at acceptable quality and pricing levels in order to meet commercial demand;
- our ability to ensure that the supply chain for these products efficiently and consistently delivers the products to our clients;
- our ability to deploy and support a qualified sales force;
- our ability to maintain fees and discounts payable to distributors who distribute these products, as well as to group purchasing organizations, at commercially reasonable levels;
- warnings or limitations that may be required to be added to the FDA-approved labeling of these products;
- the occurrence of adverse side effects or inadequate therapeutic efficacy of these products, and any resulting product liability claims or product recalls; and

- our ability to achieve hospital formulary acceptance for these products, and to the extent third-party payers separately cover and reimburse for these products, the availability of adequate levels of reimbursement for these products from third-party payers.

Any disruption in our ability to generate net sales from the sale of these products or lack of success in its commercialization will have a substantial adverse impact on our business, financial condition, results of operations and cash flows.

Aastrom's existing business' relationships and the CTRM business' relationships, including client relationships, may be subject to disruption due to uncertainty associated with the acquisition.

Parties with which Aastrom or Sanofi, as the prior owner of the CTRM business, do business may experience uncertainty associated with the acquisition, including with respect to current or future business relationships with us, the CTRM business, or the combined business. These business relationships may be subject to disruption as clients and others may attempt to negotiate changes in existing business relationships or consider entering into business relationships with parties other than Aastrom, the CTRM business, or the combined business, including our competitors or those of the CTRM business. These disruptions could have a material adverse effect on the businesses, operating results, and financial condition of the combined business.

We may have difficulty attracting, motivating and retaining executives and other key employees in light of the acquisition.

Uncertainty about the effect of the acquisition on Aastrom's and the CTRM business' employees may have an adverse effect on the combined business resulting from the acquisition. This uncertainty may impair our ability to attract, retain and motivate key personnel in the months after the merger for the combined entity. Employee retention may be particularly challenging as our employees may experience uncertainty about their future roles with the combined business. We have made offers of employment to each of the CTRM business' employees, and we have implemented employment compensation arrangements in connection with the acquisition to encourage these individuals' continued employment with us. We cannot, however, provide assurances that these arrangements will sufficiently incentivize the employees to remain with us after the acquisition. If key employees depart because of issues relating to the uncertainty and difficulty of integration, financial incentives or a desire not to become employees of the combined business, we may incur significant costs in identifying, hiring and retaining replacements for departing employees, which could substantially reduce or delay our ability to realize the anticipated benefits of the acquisition.

Risks Related to the Acquired CTRM Business

The continued development of our acquired products and any future product candidates is subject to uncertainty because autologous cell therapy is inherently variable.

When manufacturing an autologous cell therapy, the number and the composition of the cell population varies from patient to patient, in part due to the age of the patient, since the therapy is dependent on patient specific physiology. Such variability in the number and composition of these cells could adversely affect our ability to manufacture autologous cell therapies in a cost-effective manner and meet acceptable product release specifications for use in a clinical trial or, if approved, for commercial sale. As a consequence, the development and regulatory approval process for autologous cell therapy products could be delayed or may never be completed.

Biologics products are complex and difficult to manufacture.

Manufacturing biologic products, such as our acquired products, is highly complex. Unlike products that rely on chemicals for efficacy, such as most pharmaceuticals, biologics are difficult to characterize due to the inherent variability of biological input materials. Difficulty in characterizing biological materials or their interactions creates greater risk in the manufacturing process. We attempt to mitigate risk associated with the manufacture of biologics by continuing to improve the characterization of all of our input materials, utilizing multiple vendors for supply of qualified biological materials, and manufacturing some of these materials ourselves. However, there can be no assurance that we will be able to maintain adequate sources of biological materials or that biological materials that we maintain in inventory will yield finished products that satisfy applicable product release criteria. Our inability to obtain necessary biological materials or to successfully manufacture biologic products that incorporate such materials could have a material adverse effect on our results of operations.

In order to market MACI in the United States, the FDA requires us to file a BLA.

The FDA approved Carticel as a biological product, for which we currently hold a biologics license. MACI is also subject to the FDA's biological product requirements, which will require us to submit a new BLA. To the extent the FDA regulates MACI as a biological product and requires us to file a BLA, we would be unable to sell MACI unless and until we receive BLA approval from the FDA, which would be complex, time-consuming and expensive. For example, the FDA may require that we conduct one or more clinical trials in support of approval of a BLA, which would result in the expenditure of additional financial resources and extended timelines to commercialization.

Clinical trial failures can occur at any stage of the testing and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent the continued commercialization of our acquired products or future therapeutic product candidates.

With respect to any clinical trials affecting our acquired products or any future product candidates, failures or delays can occur at any stage of the trials, and may be directly or indirectly caused by a variety of factors, including but not limited to:

- delays in securing clinical investigators or trial sites for our clinical trials;

- delays in obtaining Institutional Review Board (IRB) and other regulatory approvals to commence a clinical trial;

- slower than anticipated rates of patient recruitment and enrollment, or failing to reach the targeted number of patients due to competition for patients from other trials;
- limited or no availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third party payers for the use of agents used in our clinical trials;
- negative or inconclusive results from clinical trials;
- unforeseen side effects interrupting, delaying, or halting clinical trials of any future therapeutic product candidates, and possibly resulting in the FDA or other regulatory authorities denying approval of any future therapeutic product candidates;
- unforeseen safety issues;
- approval and introduction of new therapies or changes in standards of practice or regulatory guidance that render our clinical trial endpoints or the targeting of our proposed indications obsolete;
- inability to monitor patients adequately during or after treatment or problems with investigator or patient compliance with the trial protocols;
- inability to replicate in large controlled studies safety and efficacy data obtained from a limited number of patients in uncontrolled trials;
- inability or unwillingness of medical investigators to follow our clinical protocols; and
- unavailability of clinical trial supplies.

The potential of our acquired products and any future products under development to treat conditions may not be realized.

We are evaluating and will continue to evaluate the potential of our acquired products and any future products under development. These products are susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate efficacy or other characteristics that may prevent or limit their commercial use, or if required, marketing approval. If the treatment potential of our acquired products is not realized, the value of our technology, our development programs and our acquired products could be significantly reduced. Because our acquired products are comprised of human tissue, any negative developments regarding the therapeutic potential or side effects of human tissue products could have a material adverse effect on our business, financial condition and results of operations.

Technological and medical developments or improvements in conventional therapies could render the use of cell therapy and the CTRM products and planned products obsolete.

Advances in other treatment methods or in disease prevention techniques could significantly reduce or entirely eliminate the need for our cell therapy CTRM products, planned products and therapeutic efforts. There is no assurance that cell therapies will achieve the degree of success envisioned by us in the treatment of disease. Nor is there any assurance that new technological improvements or techniques will not render obsolete the processes currently used by us, the need for our CTRM products or our planned products. Additionally, technological or medical developments may materially alter the commercial viability of our technology or CTRM products, and require us to incur significant costs to replace or modify equipment in which we have a substantial investment. The

occurrence of any of these factors may have a material adverse effect on our business, operating results and financial condition.

The manufacture of cell therapy products is characterized by inherent risks and challenges and has proven to be a costly endeavor relative to manufacturing other therapeutics products. We have limited experience in manufacturing products for commercial purposes and we cannot assure you that we will be able to successfully and efficiently manage the manufacturing of our acquired products, either ourselves or through third-party contractors with whom we may enter into strategic relationships.

The manufacture of cell therapy products, such as our acquired products, is characterized by inherent risks and challenges such as autologous raw material inconsistencies, logistical challenges, significant quality control and assurance requirements, manufacturing complexity, and significant manual processing. Additionally, we have limited experience in manufacturing products for commercial purposes and could experience difficulties in the continued development or manufacturing of our acquired products that could impair our ability to successfully commercialize these products. Because our experience in manufacturing is limited, we may encounter unforeseen difficulties in our efforts to efficiently manage the manufacturing of our acquired products or have to rely on third-party contractors over which we may not have direct control to manufacture our acquired products. Moreover, there can be no assurance that we or any third-party contractors with whom we enter into strategic relationships will be successful in streamlining manufacturing operations and implementing efficient, low-cost manufacturing capabilities and processes that will enable us to meet the quality, price and production standards or production volumes to achieve profitability. Our failure to develop these manufacturing processes and capabilities in a timely manner could prevent us from achieving our growth and profitability objectives as projected or at all.

The acquisition will result in the expansion of our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of March 31, 2014, we had 38 full-time employees. As a result of the acquisition, we expect a significant increase in our employee base, and such growth will impose significant additional responsibilities on our management, including the need to maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The effective management of the CTRM business could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced, and we may not be able to implement

our business strategy. Our future financial performance and our ability to commercialize our acquired products and our other product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage our current growth.

We are subject to significant regulation with respect to the manufacturing of our acquired products.

All of those involved in the preparation of a cellular therapy for clinical trials or commercial sale, including our existing supply contract manufacturers and clinical trial investigators, are subject to extensive continuing government regulations by the FDA and comparable agencies in other jurisdictions. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Our facilities and quality systems and the facilities and quality systems of some or all of our third party contractors and suppliers must pass inspection for compliance with the applicable regulations as a condition of FDA approval of our acquired products. The FDA also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third party contractors. In addition, the FDA may, at any time, audit or inspect a manufacturing facility involved with the preparation of our acquired products or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Recently, our manufacturing facility in Cambridge, Massachusetts was inspected by the FDA, resulting

in the issuance of an FDA 483 List of Inspectional Observations. We are undertaking remedial measures to improve our manufacturing process and communicate those measures to the FDA, but the FDA may decide that our remedial measures should be revised or expanded, or the FDA may not find our corrective actions to be adequate. Generally, if any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulation occurs independent of such an inspection or audit, we or the FDA may require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales, recalls, warning letters, market withdrawals, seizures or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

Our business, financial condition, results of operation and cash flows could be significantly and negatively affected by substantial governmental regulations.

Our acquired products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. Overall, there appears to be a trend toward more stringent regulation worldwide, and we do not anticipate this trend to dissipate in the near future.

In general, the development, testing, labeling, manufacturing and marketing of our acquired products are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. The regulatory process requires the expenditure of significant time, effort and expense to bring new products to market. For example, FDA approved Epicel as a HUD, which is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. HUD treatment is subject to additional FDA requirements, such as recordkeeping, reporting, labeling, as well as limited use of a HUD when approved by an Institutional Review Board, or IRB, that oversees medical treatment. Failure to meet FDA requirements pertaining to a HUD could result in the suspension or revocation of the HUD. While Epicel has been approved as a HUD, oversight is conducted by the FDA's Center for Biologics Evaluation and Research (CBER) because it is a cell-based product.

If HUD approval is suspended or revoked, Epicel would require an approved premarket approval application (or PMA) in order to be made commercially available, or an approved BLA. The PMA and BLA processes are costly, lengthy and uncertain. A PMA must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use. A BLA must be supported by substantial evidence of clinical safety and effectiveness for its intended use as proven through one or more clinical trials in a statistically significant patient population. If the HUD approval for Epicel was withdrawn, and we were unable to obtain approval of a PMA or BLA, we could not offer Epicel for sale in the U.S.

We are also required to implement and maintain stringent reporting, labeling and record keeping procedures. More specifically, in the United States, both before and after a product is commercially released, we have ongoing responsibilities under FDA regulations. Compliance with the FDA's requirements, including the FDA's cGMP recordkeeping regulations, labeling and promotional requirements and adverse event reporting regulations, is subject to continual review and is monitored rigorously through periodic inspections by the FDA. Our failure to comply with U.S. federal, state and foreign governmental regulations could lead to the issuance of warning letters or untitled letters, the imposition of injunctions, suspensions or loss of regulatory clearance or approvals, product recalls, termination of distribution, product seizures or civil penalties. In the most extreme cases, criminal sanctions or closure of our manufacturing facility are possible.

In addition, the pharmaceutical, biologic and medical industries also are subject to many complex laws and regulations governing Medicare and Medicaid reimbursement and targeting healthcare fraud and abuse, with these laws and regulations being subject to interpretation. In many instances, the industry does not have the benefit of significant regulatory or judicial interpretation of these laws and regulations. In certain public statements, governmental authorities have taken positions on issues for which little official interpretation was previously available. Some of these positions appear to be inconsistent with common practices within the industry but have not previously been challenged.

Various federal and state agencies have become increasingly vigilant in recent years in their investigation of various business practices, such as the federal Anti-kickback Statute and the federal False Claims Act. Governmental and regulatory actions against us can result in various actions that could adversely impact our operations, including:

- the recall or seizure of products;
- the suspension or revocation of the authority necessary for the production or sale of a product;

- the suspension of shipments from particular manufacturing facilities;
- the imposition of fines and penalties;
- the delay of our ability to introduce new products into the market;
- our exclusion or the exclusion of our acquired products from being reimbursed by federal and state healthcare programs (such as Medicare, Medicaid, Veterans Administration, or VA, health programs and Civilian Health and Medical Program Uniformed Service, or CHAMPUS); and
- other civil or criminal prosecution or sanctions against us or our employees, such as fines, penalties or imprisonment.

Any of these actions, in combination or alone, or even a public announcement that we are being investigated for possible violations of these laws, could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In the United States, if the FDA were to conclude that we are not in compliance with applicable laws or regulations or that any of the CTRM products are ineffective or pose an unreasonable health risk, the FDA could ban such products, detain or seize adulterated or misbranded products, order a recall, repair, replacement, or refund of payment of certain products, refuse to grant pending approval applications, refuse to provide certificates to foreign governments for exports, and/or require us to notify healthcare professionals and others that the products present unreasonable risks of substantial harm to the public health. The FDA may also impose operating restrictions on a companywide basis, enjoin and restrain certain violations of applicable law pertaining to the CTRM products and assess civil or criminal penalties against our officers, employees or us. The FDA may also recommend prosecution to the United States Department of Justice (DOJ). Adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our acquired products.

In many of the foreign countries in which our acquired products are marketed, we are subject to regulations affecting, among other things, clinical efficacy, product standards, packaging requirements, labeling requirements, import/ export restrictions, tariff regulations, duties and tax requirements. Many of the regulations applicable to the CTRM products in these countries, such as the Medicinal Products Directive and the ATMP guidelines, governing products in the European Union, are similar to those of the FDA. In addition, in many countries the national health or social security organizations require our acquired products to be qualified before they can be marketed with the benefit of reimbursement eligibility. Failure to receive or delays in the receipt of relevant foreign qualifications also could have a material adverse effect on our business, financial condition, results of operations and cash flows.

As both the U.S. and foreign government regulators have become increasingly stringent, we may be subject to more rigorous regulation by governmental authorities in the future. Our acquired products and our operations are also often subject to the rules of industrial standards bodies, such as the International Standards Organization, or ISO. If we fail to adequately address any of these regulations, our business will be harmed.

Changes to our acquired products may require new regulatory approvals or may require us to recall or cease marketing our acquired products until approvals are obtained.

Modifications to our acquired products may require new regulatory approvals, including supplements to investigational new drug (IND) applications, or supplements to our BLA or Humanitarian Device Exemption application, or require us to recall or cease marketing the modified products until these approvals are obtained. We may not be able to obtain those additional approvals for the changes or additional indications in a timely manner, or at all. Obtaining approvals can be a time consuming process, and delays in obtaining required future approvals would adversely affect our ability to introduce new or improved products in a timely manner, which in turn would harm our future growth.

If we or our suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if we experience unanticipated problems with our acquired products, these products could be subject to restrictions or withdrawal from the market.

The manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for each of our acquired products is subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our suppliers are required to comply with cGMP and Good Tissue Practice (GTP) regulations for the manufacture of our acquired products and other regulations which cover requirements such as the methods and documentation pertaining to production controls, labeling, packaging, storage and shipment of any product for which we obtain clearance or approval. Regulatory bodies, such as the FDA, enforce the cGMP, GTP and other regulations through periodic inspections. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP and adherence to commitments made in the BLA. If we or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- client notifications for repair, replacement, refunds;

- recall, detention or seizure of our acquired products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for approval of new products or modified products;
- operating restrictions;
- withdrawing product approvals that have already been granted;

- refusal to approve a pending marketing application, such as a BLA or supplements to a BLA submitted by us;
- refusal to grant export approval for our acquired products; or
- criminal prosecution.

If any of these actions were to occur it would harm our reputation and cause our CTRM product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our acquired products on a timely basis and in the required quantities, if at all. In addition, we may be required to conduct costly post-approval studies, and post-market surveillance to monitor the safety or effectiveness of our acquired products. We also must comply with adverse event reporting requirements, which require that we report certain adverse events involving patient use or treatment with our acquired products. Later discovery of previously unknown problems with our acquired products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as cGMP or GTP, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

Our CTRM products may be used by physicians for indications that are not approved by the FDA. If the FDA finds that we marketed our CTRM products in a manner that promoted off-label use, we may be subject to civil or criminal penalties.

Under the Federal Food, Drug, and Cosmetic Act and other laws, we are prohibited from promoting our acquired products for off-label uses. This means, for example, that we may not make claims about the use of Carticel or Epicel outside of their approved indications, and we may not proactively discuss or provide information on off-label uses of Carticel or Epicel, with very specific and limited exceptions. The FDA does not, however, restrict physicians from prescribing products for off-label uses in the practice of medicine. Should the FDA determine that our activities constitute the promotion of off-label use, the FDA could bring action to prevent us from distributing Carticel or Epicel for the off-label use and could impose fines and penalties on us and our executives. In addition, failure to follow FDA rules and guidelines relating to promotion and advertising can result in, among other things, the FDA's refusal to approve a product, the suspension or withdrawal of an approved product from the market, product recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecutions.

If the Office of Inspector General within the Department of Health and Human Services, the DOJ, or another federal or state agency determines that we have promoted off-label use of our CTRM products, we may be subject to various penalties, including civil or criminal penalties, and the off-label use of our CTRM products may result in injuries that lead to product liability suits, which could be costly to our business.

In addition to the FDA restrictions on marketing of Carticel and Epicel, several other types of state and federal healthcare laws have been applied by DOJ and state attorneys general to restrict certain marketing practices in the pharmaceutical industry. While physicians may prescribe products for off-label uses and indications, if other federal or state regulatory authorities determine that we have engaged in off-label promotion through remuneration, kickbacks or other monetary benefits to prescribers, we may be subject to civil or criminal penalties and could be prohibited from participating in government healthcare programs such as Medicaid and Medicare. In addition, government agencies or departments could conclude that we have engaged in off-label promotion and, potentially, caused the submission of false claims. Even if we are successful in resolving such matters without incurring penalties, responding to investigations or prosecutions will likely result in substantial costs and could significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results, financial condition and ability to finance our operations. In

addition, the off-label use of our CTRM products may increase the risk of injury to patients, and, in turn, the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention and result in substantial damage awards against us.

The price and sale of any of our acquired products may be limited by health insurance coverage and government regulation.

Maintaining and growing sales of our acquired products will depend in large part on the availability of adequate coverage and the extent to which third-party payers, including health insurance companies, health maintenance organizations (HMOs), and government health administration authorities such as Medicare and Medicaid, private insurance plans and managed care programs will pay for the cost of the products and related treatment. Hospitals and other healthcare provider clients that purchase our acquired products typically bill various third-party payers to cover all or a portion of the costs and fees associated with the procedures in which such products are used, including the cost of the purchase of these products. Third-party payers are also increasingly attempting to contain healthcare costs by demanding price discounts or rebates and limiting both coverage and the amounts that they will pay for certain products, and, as a result, they may not cover or continue to provide adequate payment for our acquired products. We might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of our acquired products and any future products to such payers' satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources. Our acquired products and future products might not

ultimately be considered cost-effective. Adequate third-party reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in our acquired products and future product development. If coverage and adequate reimbursement are not available, reimbursement is available only to limited levels, or if our costs of production increase faster than increases in reimbursement levels, we may not be able to successfully grow the sales of our acquired products or commercialize any product candidates for which marketing approval is obtained.

Coverage decisions and payment amounts are established at the discretion of the individual third-party payer, and the regulations that govern pricing, coverage and reimbursement vary widely from country to country. Many private payers in the United States, however, use coverage decisions and payment amounts determined by the Centers for Medicare & Medicaid Services (CMS), as guidelines in setting their coverage and reimbursement policies. As the portion of the U.S. population over the age of 65 and eligible for Medicare continues to grow, we may be more vulnerable to coverage and reimbursement limitations imposed by CMS. While certain procedures using our acquired products are currently covered by Medicare and other third-party payers, future action by CMS or other government agencies may diminish payments to physicians, outpatient centers and/or hospitals for covered services. As a result, we cannot be certain that the procedures performed with our acquired products will be reimbursed at a cost-effective level or reimbursed at all.

Furthermore, the healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with service providers. Therefore, we cannot be certain that the procedures performed with our acquired products will be reimbursed at a cost-effective level. Nor can we be certain that third-party payers using a methodology that sets amounts based on the type of procedure performed, such as those utilized by Medicare and in many privately managed care systems, will view the cost of our acquired products to be justified so as to incorporate such costs into the overall cost of the procedure. Moreover, we are unable to predict what changes will be made to the reimbursement methodologies used by third-party payers in the future.

Tissue based products are regulated differently in different countries. These requirements may be costly and result in delay or otherwise preclude the distribution of our acquired products in some foreign countries, any of which would adversely affect our ability to generate operating revenues.

Tissue based products are regulated differently in different countries. Many foreign jurisdictions have a different and may have a more difficult regulatory pathway for human tissue based products, which may prohibit the distribution of these products until the applicable regulatory agencies grant marketing approval, or licensure. The process of obtaining regulatory approval is lengthy, expensive and uncertain, and we may never seek such approvals, or if we do, we may never gain those approvals. Any adverse events in our clinical trials for a future product under development could negatively impact our acquired products.

Unintended consequences of recently adopted healthcare reform legislation in the U.S. may adversely affect our business.

The United States and some foreign jurisdictions are considering, or have enacted, a number of legislative and regulatory proposals, resulting from political and economic influences, to change the healthcare system in ways that could affect our ability to sell our acquired products. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA) which substantially changes the way healthcare is financed by both governmental and private insurers, encourages improvements in the quality of healthcare items and services, and significantly impacts the biotechnology and medical industries. The PPACA includes, among other things, the following measures:

- a 2.3% excise tax on the sale price of medical devices to be paid by any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions;
- a new Patient-Centered Outcomes Research Institute to oversee, identify research priorities and conduct comparative clinical effectiveness research;
- new reporting and disclosure requirements on biological product and device manufacturers, also known as the Sunshine Act, for any payment or other “transfer of value” made or distributed to physicians and teaching hospitals, as well as reporting of certain physician ownership interests with data collection requirements beginning in 2013 and the first reports due in 2014;
- payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models;
- an independent payment advisory board that will submit recommendations to Congress to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate; and
- a new abbreviated pathway for the licensure of biological products that are demonstrated to be biosimilar or interchangeable with a licensed biological product.

These provisions could meaningfully change the way healthcare is delivered and financed. If the legislation causes certain unintended consequences or has an indirect impact on us, it could have a material adverse effect on our business, financial condition and results of operations.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation’s automatic reduction to several government programs. This includes reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 (ATRA) which, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

In the future there may continue to be additional proposals relating to the reform of the U.S. healthcare system. Certain of these proposals could limit the price that we are able to charge for our acquired products, or the amount of reimbursement available for our acquired products, and could limit the acceptance

and availability of our acquired products for various indications. The adoption of some or all of these proposals could have a material adverse effect on our business, results of operations and financial condition.

Competitor companies or hospitals may be able to take advantage of the EU rules permitting sales of unlicensed medicines for individual patients to sell competing products without a marketing authorization.

The EU medicines rules allow individual member states to permit the supply of a medicinal product without a marketing authorization to fulfill special needs, where the product is supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of a healthcare professional and for use by an individual patient under his direct personal responsibility.

This may, in certain countries, also apply to products manufactured in a country outside the EU and imported to treat specific patients or small groups of patients. In addition, advanced therapy medicinal products do not need a marketing authorization if they are prepared on a non-routine basis and are used within the same EU member state in a hospital in accordance with a medical prescription for an individual patient (named patient basis).

These exemptions could allow our competitors to make sales in the EU without having obtained a marketing authorization and without undergoing the expense of clinical trials, especially if those competitors have cell processing facilities in the relevant EU member state. Similarly, certain hospitals may be able to compete with us on the basis of these rules. Because any such sales would be made without a marketing authorization, there would be no need for the competitor company or hospital to refer to the clinical data in our marketing authorization dossiers, and so any data exclusivity protection that we may obtain for our acquired products would not prevent such competing sales.

Risks Related to the CTRM business' Manufacturing Activities

The manufacture of cell therapy products is characterized by inherent risks and challenges. We will not be able to achieve profitability if we are unable to successfully manage the manufacturing of our acquired products, either ourselves or through third-party contractors with whom we may enter into strategic relationships.

The manufacture of cell therapy products, such as our acquired products, is characterized by inherent risks and challenges such as autologous raw material inconsistencies, logistical challenges, significant quality control and assurance requirements, manufacturing complexity, and significant manual processing. These variables and certain uncertainties associated with the manufacture of our acquired products may result in outcomes that have a material adverse effect on our business, operating results, financial condition and prospects.

Additionally, we have no long-term experience in manufacturing products for commercial purposes and could experience difficulties in the continued development or manufacturing of our acquired products that could impair our ability to successfully commercialize these products. Because our experience in manufacturing is limited, we may encounter unforeseen difficulties in our efforts to efficiently manage the manufacturing of our acquired products or have to rely on third-party contractors over which we may not have direct control to manufacture our acquired products. Moreover, there can be no assurance that we or any third-party contractors with whom we enter into strategic relationships will be successful in streamlining manufacturing operations and implement efficient, low-cost manufacturing capabilities and processes that will enable us to meet the quality, price and production standards or production volumes at acceptable manufacturing costs to achieve profitability. Our failure to develop these manufacturing processes and capabilities in a timely manner could prevent us from achieving our growth and profitability objectives as projected or at all.

In order to potentially increase our revenue from the sales of our acquired products or commercialize any future product candidates, we may need to increase our manufacturing capacity or improve our manufacturing capabilities, which will require significant expenditures and regulatory approval.

We currently have limited manufacturing experience with our acquired products. In addition, our current manufacturing process is primarily a manual process. While we expect that our current manufacturing capacity is sufficient for our projected growth in the near term, we may need to add manufacturing capacity to potentially increase our revenue from the sales of our acquired products and any future products, and to commercialize any future product candidates. We also are developing enhancements and alternatives to our current manual manufacturing process. If we have difficulties in increasing our manufacturing capacity and improving our

capabilities, we will be limited in our ability to potentially increase our revenue from our acquired products, as well as any new product candidates, if they are approved for marketing; and we may not be able to decrease our manufacturing costs. These difficulties could adversely affect our financial performance and damage our reputation. Even if we are successful in developing such enhancements or finding alternatives to our current process, such manufacturing changes will require additional expenditures, for which we may be required to seek external financing. In addition, our ability to increase our manufacturing capacity or modify our manufacturing processes will be subject to additional FDA review and approval.

We have limited manufacturing capacity and our research, development and manufacturing operations in the U.S. depend on one facility. If such facility is destroyed or we experience any manufacturing difficulties, disruptions or delays, this could limit supply of our acquired products or adversely affect our ability to conduct our clinical trials and our business would be adversely impacted.

We presently intend to conduct all our CTRM research, development and manufacturing operations in the U.S. in one facility located in Cambridge, Massachusetts. As a result, all of the commercial manufacturing of the U.S. approved products for the U.S. market would take place at a single U.S. facility. In addition, clinical trials for any future product candidates would primarily depend upon the manufacturing of such product candidates in the same facility. If regulatory, manufacturing or other problems require us to discontinue production at that facility, we will not be able to supply our CTRM products to our patients or have supplies for any clinical trials, which would adversely impact our business. If this facility or the equipment in it is significantly damaged or destroyed by fire, flood, power loss or similar events, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace our facility at all. In the event of a temporary or protracted loss of this facility or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to

comply with the applicable regulatory and quality standard requirements whereby validation and FDA approval would be required before any products manufactured at that facility could be made commercially available.

If our manufacturing and storage facility is damaged or destroyed, our business and prospects would be negatively affected.

If our manufacturing and storage facility or the equipment in the facility were to be significantly damaged or destroyed, we could suffer a loss of some or all of the stored product, raw and other materials, and work in process.

Currently, we maintain insurance coverage totaling $4.0 million in Denmark and $32.0 million in the U.S. against damage to our property and equipment (recently increased by an additional $4.0 million in the U.S. as a result of the Transaction), an additional $1.0 million to cover business interruption and extra expenses, and $1.0 million to cover R&D restoration expenses. If we have underestimated our insurance needs, we will not have sufficient insurance to cover losses above and beyond the limits on our policies.

We could incur significant costs complying with environmental and health and safety requirements, or as a result of liability for contamination or other harm caused by hazardous materials that we use.

Our research and development and manufacturing processes involve the use of hazardous materials. We are subject to federal, state, local and foreign environmental requirements, including regulations governing the use, manufacture, handling, storage and disposal of hazardous materials, discharge to air and water, the cleanup of contamination and occupational health and safety matters. We cannot eliminate the risk of contamination or injury resulting from hazardous materials, and we may incur liability as a result of any contamination or injury. Under some environmental laws and regulations, we could also be held responsible for costs relating to any contamination at our past or present facilities and at third party waste disposal sites where we have sent wastes. These could include costs relating to contamination that did not result from any violation of law, and in some circumstances, contamination that we did not cause. We may incur significant expenses in the future relating to any failure to comply with environmental laws. Any such future expenses or liability could have a significant negative impact on our financial condition. The enactment of stricter laws or regulations, the stricter interpretation of existing laws and regulations or the requirement to undertake the investigation or remediation of currently unknown environmental contamination at our own or third party sites may require us to make additional expenditures, which could be material.

Risks Related to the CTRM Business' Operations and Industry

In addition to costs incurred in integration, product development and management of the regulatory approval and reimbursement processes, we will incur additional operating expenses in connection with the operation of the CTRM business.

We expect to continue to incur significant operating expenses in connection with the operation of the CTRM business, as we seek to:

- continue to develop our distribution network of third party distributors and independent sales professionals for the distribution of our acquired products and any future products;
- expand our internal sales and marketing capabilities as we build an internal sales and marketing organization;
- hire additional manufacturing, quality control, pharmacovigilance, regulatory affairs, quality assurance, and management personnel as necessary to maintain or expand our processing operations;
- maintain our facility as an FDA compliant and validated product manufacturing facility; and
- expand and protect our intellectual property portfolio for our acquired products.

Our ability to scale up our production capabilities for larger quantities of these products remains to be proven. Our costs in marketing and distributing products will also increase as production increases.

Ethical, legal, social and other concerns surrounding the use of human tissue in synthetic biologically engineered products may negatively affect public perception of us or our acquired products, or may result in increased scrutiny of our acquired products and any future product candidates from a regulatory perspective, thereby reducing demand for our acquired products, restricting our ability to market our acquired products, or adversely affecting the market price for our common stock.

The commercial success of our acquired products depends in part on general public acceptance of the use of human tissue for the treatment of human diseases and other conditions. While not as controversial as the use of embryonic stem cells and fetal tissue, the use of adult tissue has been the subject of substantial debate regarding related ethical, legal and social issues. We do not use embryonic stem cells or fetal tissue, but the public may not be able to, or may fail to, differentiate our autologous use of adult tissue from the use by others of embryonic stem cells or fetal tissue. This could result in a negative perception of our company or our acquired products.

Future adverse events in the field of cellular based therapy or changes in public policy could also result in greater governmental regulation of our acquired products and potential regulatory uncertainty or delay relating to any required testing or approval.

Our competitors in the medical and biotechnology industries may have superior products, manufacturing capabilities, financial resources or marketing positions. If we are unable to continue to develop and market new products and technologies in a timely manner, the demand for our acquired products may decrease or our acquired products could become obsolete, and our revenue may decline.

The market for our acquired products is highly competitive. Our competitors in the medical and biotechnology industries may have superior products, research and development, manufacturing, and marketing capabilities, and financial resources or marketing positions. If we are unable to continue to develop and market new products and technologies in a timely manner, the demand for our acquired products may decrease or our acquired products could become obsolete, and our revenue may decline.

Carticel, MACI or any other product candidate for which we seek approval as a biologic, may face competition sooner than anticipated.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCI Act, as part of the PPACA, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCI Act, an application for a biosimilar product cannot be approved by the FDA until twelve years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement the BPCI Act may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products. While the BCPI Act provides for a twelve-year period of exclusivity, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider any of our future product candidates to be a reference product for competing products, potentially creating the opportunity for competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Our acquired products represent new classes of therapy that the marketplace may not understand or accept. Furthermore, the success of our acquired products is dependent on wider acceptance by the medical community.

While, the CTRM business has had some success commercializing its products, the broader market may not understand or accept our acquired products. Our acquired products represent novel treatments or therapies and compete with a number of more conventional products and therapies manufactured and marketed by others. The novel nature of our acquired products creates significant challenges in regards to product development and optimization, manufacturing, government regulation, and third-party reimbursement. As a result, the commercialization of our current products and development pathway for our potential products may be subject to increased scrutiny, as compared to the pathway for more conventional products.

The degree of market acceptance of any of our marketed or potential products will depend on a number of factors, including:

- the clinical safety and effectiveness of our acquired products and their perceived advantage over alternative treatment methods;
- our ability to convince health care providers that the use of our acquired products in a particular procedure is more beneficial than the standard of care or other available methods;
- our ability to explain clearly and educate others on the autologous use of patient-specific human tissue, to avoid potential confusion with and differentiate ourselves from the ethical controversies associated with human fetal tissue and engineered human tissue;
- adverse reactions involving our acquired products or the products or product candidates of others that are human tissue based;
- our ability to supply a sufficient amount of our CTRM product to meet regular and repeated demand in order to develop a core group of medical professionals familiar with and committed to the use of our acquired products; and
- the cost of our acquired products and the reimbursement policies of government and third-party payers.

If patients or the medical community do not accept our potential products as safe and effective for any of the foregoing reasons, or for any other reason, it could affect our sales, having a material adverse effect on our business, financial condition and results of operations. While acceptance by the medical community may be fostered by broad evaluation via peer-reviewed literature, we may not have the resources to facilitate sufficient publication.

We are dependent on our key manufacturing, quality and other management personnel in the CTRM business, and the loss of any of these individuals could harm our business.

We are dependent on the efforts of our key management and manufacturing and quality staff. The loss of any of these individuals, or our inability to recruit and train additional key personnel in a timely manner, could materially and adversely affect our business and our future prospects. In the future, we may need to seek additional manufacturing and quality staff members. There is a high demand for highly trained manufacturing and quality personnel in our industry. We do not know whether we will be able to attract, train and retain highly qualified manufacturing and quality personnel in the future, which could have a material adverse effect on our business, financial condition and results of operations. A loss of one or more of our key personnel could severely and negatively impact our operations. Our key personnel are employed "at-will," and any of them may elect to pursue other opportunities at any time. We have no present intention of obtaining key man life insurance on any of our key management, manufacturing, quality or other personnel.

If we are made aware of adverse events of unanticipated severity or frequency, including a death or a serious injury, we are required to report such events to the FDA, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA adverse event reporting regulations, manufacturers of biological products and medical devices are required to report to the FDA information pertaining to adverse events of unanticipated severity or frequency, including deaths or serious injuries, that may or may not be related to the use of their products. All manufacturers placing biological products or medical devices in the market in the European Union are similarly required to report any serious or potentially serious incidents involving their products to the relevant regulatory authority in whose jurisdiction the incident occurred. Any such adverse event involving our acquired products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Adverse events involving our acquired products have been reported to us in the past, and we cannot guarantee that they will not occur in the future. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

The use of our acquired products may expose us to product liability claims, and we may not be able to obtain adequate insurance.

We face an inherent risk of product liability claims. We derive the raw materials for our acquired products from patients serving as their own donors, the production process is complex, and the handling requirements are specific, all of which increase the likelihood of quality failures and subsequent product liability claims.

We may not be able to obtain or maintain product liability insurance on acceptable terms with adequate coverage or at all. If we are unable to obtain insurance, or if claims against us substantially exceed our coverage, then our business could be adversely impacted. Whether or not we are ultimately successful in any product liability litigation, such litigation could consume substantial amounts of our financial and managerial resources and could result in, among other things:

- significant awards against us;
- substantial litigation costs;
- recall of the product;
- injury to our reputation;
- withdrawal of clinical trial participants; or
- adverse regulatory action.

Any of these results could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to the CTRM business' Intellectual Property

We have no patent protection for Epicel.

We have no issued patents or pending patent applications relating to Epicel. While we attempt to protect our proprietary information as trade secrets through certain agreements with our employees, consultants, agents and other organizations to which we disclose our proprietary information, we cannot give any assurance that these agreements will provide effective protection for our proprietary information in the event of unauthorized use or disclosure of such information. If other cultured epidermal autografts are approved and marketed, we will be unable to prevent them from competing with Epicel in the marketplace. We expect that the presence of one or more competing products would reduce our market share and could negatively impact price levels and third party reimbursement policies for Epicel, any of which would materially affect our business.

Our issued patents relating to Carticel and MACI will expire soon and may be insufficient to protect our business.

We have issued patents in the United States and in certain foreign countries that relate to the combinations of chondrocytes and collagen membranes used in Carticel and MACI. However, the issued patents relating to Carticel are scheduled to expire by August of 2016 in the U.S. and by 2022 in Europe. Furthermore, the issued patents relating to MACI are scheduled to expire by August of 2016 in the U.S. and by August of 2017 in Europe. When these patents expire we may be subject to increased competition and our opportunity to establish or maintain product revenue could be substantially reduced or eliminated.

The patents we own may not be of sufficient scope or strength to provide us with significant commercial protection or commercial advantage, and competitors may be able to design around our patents or develop products that provide outcomes that are similar to ours without infringing on our intellectual property rights. In addition, we cannot be certain that any of our pending patent applications will be issued or that the scope of the claims in our pending patent applications will not be significantly narrowed or determined to be invalid.

Given our patent position in regard to our acquired products, if we are unable to protect the confidentiality of our proprietary information and know-how related to these products, our competitive position would be impaired and our business, financial condition and results of operations could be adversely affected.

Some of our technology, including our knowledge regarding the processing our acquired products, is unpatented and is maintained by us as trade secrets. In an effort to protect these trade secrets, we require our employees, consultants, collaborators and advisors to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. These agreements, however, may not provide us with adequate protection against improper use or disclosure of confidential information, and these agreements may be breached. A breach of confidentiality could affect our competitive position. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, collaborators or advisors have previous employment or consulting relationships. Also, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets would impair our competitive position and could have a material adverse effect on our business, financial condition and results of operations.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the United States Patent and Trademark Office (USPTO) and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our acquired products or any future product candidates, our competitive position would be adversely affected.

With respect to MACI, if we are unable to obtain and enforce patents and to protect our trade secrets, others could use our technology to compete with us, which could limit opportunities for us to generate revenues by licensing our technology and selling products.

Our success will depend in part on our ability to obtain and enforce patents and maintain trade secrets in the United States and in other countries. If we are unsuccessful in obtaining and enforcing patents, our competitors could use our technology and create products that compete with our acquired products, without paying license fees or royalties to us.

The preparation, filing, and prosecution of patent applications can be costly and time consuming. Our limited financial resources may not permit us to pursue patent protection of all of our technology and products throughout the world.

Even if we are able to obtain issued patents covering our technology or products, we may have to incur substantial legal fees and other expenses to enforce our patent rights in order to protect our technology and products from infringing uses. We may not have the financial resources to finance the litigation required to preserve our patent and trade secret rights.

A successful challenge to our trademarks could force us to rebrand Epicel, Carticel, or MACI.

We rely on our trademarks to distinguish our acquired products from the products of our competitors, and have registered or applied to register a number of these trademarks. Third parties may challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our acquired products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing these new brands.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful and have a material adverse effect on the success of our business.

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Also, third parties may initiate legal proceedings against us to challenge the validity or scope of intellectual property rights we own or control. These proceedings can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property.

Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation

proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

We may be subject to patent infringement claims that could be costly to defend, which may limit our ability to use disputed technologies, and which could prevent us from pursuing research and development or commercialization of some of our acquired products, require us to pay licensing fees to have freedom to operate and/or result in monetary damages or other liability for us.

The success of our business will depend significantly on our ability to operate without infringing patents and other proprietary rights of others. If the technology that we use infringes a patent held by others, we could be sued for monetary damages by the patent holder or its licensee, or we could be prevented from continuing research, development, and commercialization of products that rely on that technology, unless we are able to obtain a license to use the patent. The cost and availability of a license to a patent cannot be predicted, and the likelihood of obtaining a license at an acceptable cost would be lower if the patent holder or any of its licensees is using the patent to develop or market a product with which our CTRM products would compete. If we could not obtain a necessary license, we would need to develop or obtain rights to alternative technologies, which could prove costly and could cause delays in product development, or we could be forced to discontinue the development or marketing of any products that were developed using the technology covered by the patent.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make products that are the same as or similar to our acquired products or any future product candidates, but that are not covered by the claims of the patents that we own or have exclusively licensed;

- We or any strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;

- We might not have been the first to file patent applications covering certain of our inventions;

- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

- It is possible that our pending patent applications will not lead to issued patents;

- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;

- Our competitors might conduct research and development activities in the U.S. and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- We may not develop additional proprietary technologies that are patentable; and

- The patents of others may have an adverse effect on our business.

Others may challenge our patent or other intellectual property rights or sue us for infringement.

Risks Related to an Investment in our Common Stock

The market price of the common stock of the combined company may be affected by factors different from those affecting the market price for our common stock.

Aastrom's current business differs from that of the CTRM business, and the business of the combined company will differ from that of ours, and accordingly, the results of operations for the combined company may be affected by factors different from those currently affecting the results of operations of the CTRM business and may be affected by factors different from those currently affecting our results of operations. As a result, the market price for our stock may be impacted differently in the future by those factors than it is currently.

Item 7.01. Regulation FD Disclosure.

On June 2, 2014, we issued a press release announcing the closing of the Transaction set forth in Item 2.01 of this Current Report on Form 8-K. A copy of the press release is attached hereto as Exhibit 99.1.

Pursuant to General Instruction B.2 of Form 8-K, the information filed under this item number and Exhibit 99.1 are not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, nor shall this item number and Exhibit 99.1 be incorporated by reference into our filings under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as expressly set forth by specific reference in such future filing.

Safe Harbor for Forward-Looking Statements

This Current Report on Form 8-K, including Exhibit 99.1 hereto, contains "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are typically preceded by words such as "believes," "expects," "anticipates," "intends," "will," "may," "should," or similar expressions. These forward looking statements are subject to risks and uncertainties that may cause actual future experience and results to differ materially from those discussed in these forward-looking statements. Important factors that might cause such a difference include, but are not limited to, costs related to the Transaction; the inability to integrate Aastrom's business and the CTRM business successfully; Aastrom's ability to successfully and efficiently manage the manufacturing of the acquired products; the future of the regenerative medicine industry and the role of stem cells and cellular therapy in that industry; regulatory issues, including intended applications and required approvals; and other events and factors disclosed previously and from time to time in the Company's filings with the SEC, including in this Current Report on Form 8-K under the caption "Risk Factors", in the Company's Annual Report on Form 10-K for the year ended December 31, 2013, as filed with the SEC on March 13, 2014, and the other documents filed by the Company with the SEC from time to time. Aastrom does not undertake any obligation to release publicly any revisions to such forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

Item 9.01. Financial Statements and Exhibits.

(a) *Financial statements of businesses acquired*.

a. Abbreviated financial statements of the CTRM business will be filed by amendment to this Current Report on Form 8-K (the Report) no later than 71 days following the date that this Report is required to be filed.

(b) *Pro Forma Financial Information.*

a. Unaudited abbreviated pro forma financial information will be filed by amendment to this Report no later than 71 days following the date that this Report is required to be filed.

(d) Exhibits

Exhibit Number	Description
2.1	Asset Purchase Agreement, dated as of April 19, 2014, by and between the Company and Sanofi*
10.1	Transition Services Agreement, dated as of May 30, 2014 by and between the Company and Genzyme**
10.2	Transition Supply Agreement, dated as of May 30, 2014 by and between the Company and Genzyme**
99.1	Press Release, dated June 2, 2014, announcing the closing of the purchase of the CTRM Business

* Incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the SEC on April 23, 2014.
**Schedules omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company agrees to furnish a supplemental copy of any omitted schedule to the Securities Exchange Commission upon request.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Aastrom Biosciences, Inc.

Date: June 2, 2014

By: /s/ Dominick C. Colangelo
Name: Dominick C. Colangelo
Title: Chief Executive Officer and President

TRANSITION SERVICES AGREEMENT

by and among

GENZYME CORPORATION

and

AASTROM BIOSCIENCES, INC.

Dated as of May 30, 2014

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SCHEDULES

TRANSITION SERVICES AGREEMENT

This Transition Services Agreement is dated as of May 30, 2014 (the "Execution Date"), by and between Aastrom Biosciences, Inc., a Michigan corporation ("Service Recipient"), and Genzyme Corporation, a Massachusetts corporation ("Service Provider"). Service Recipient and Service Provider are referred to in this Agreement each as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, Service Recipient and Sanofi, a French Societe anonyme ("Sanofi") have entered into an Asset Purchase Agreement dated as of April 19, 2014 (the "Asset Purchase Agreement") pursuant to which Service Recipient acquired the Transferred Assets from Sanofi and its Retained Affiliates;

WHEREAS, in connection with the transactions contemplated by the Asset Purchase Agreement, the Parties contemplate that during the Term, Service Provider will provide certain transitional services to Service Recipient in accordance with the terms and conditions set forth herein.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

For the purpose of this Agreement, the following capitalized terms have the following meanings. Capitalized terms which are used but not defined herein have the meanings ascribed to such terms in the Asset Purchase Agreement.

"Additional Services" is defined in Section 2.6.

"Agreement" means this Transition Services Agreement and includes all Transition Service Schedules, whether attached hereto or added subsequently pursuant to the terms of this Agreement.

"Asset Purchase Agreement" is defined in the recitals to this Agreement.

"Claim" is defined in Section 10.2.

"Cleared Service Recipient Personnel" is defined in Section 8.3.

"Data" is defined in Section 7.4.

"Dispute" is defined in Section 3.3.

"Effective Date" means the Closing Date.

"Execution Date" is defined in the introduction to this Agreement.

"Expenses" is defined in Section 5.2.

"Losses" is defined in Section 10.1.

"Party" and "Parties" are defined in the introduction to this Agreement.

"SDEA" is defined in Section 13.3.

"Services" means all services to be provided by Service Provider to Service Recipient as described on any Transition Service Schedule, including any Additional Services.

"Service Provider" is defined in the introduction to this Agreement.

"Service Provider Manager" is defined in Section 3.1.

"Service Provider Personnel" is defined in Section 8.2

"Service Provider Representative" is defined in Section 3.1.

"Service Recipient" is defined in the introduction to this Agreement.

"Service Recipient Manager" is defined in Section 3.1.

"Service Recipient Personnel" is defined in Section 8.2.

"Service Recipient Representative" is defined in Section 3.1.

"Service Term" is defined in Section 2.3.2.

"Term" is defined in Section 4.1.

"Transition Service Schedule" is defined in Section 2.1.

ARTICLE 2
SERVICES

2.1. Schedules and Precedence. This Agreement governs the provision of transitional Services described in the schedules attached to and made a part of this Agreement (each individual schedule, a "Transition Service Schedule"). Such Transition Service Schedules may be amended in writing from time to time by the Parties. If there is any inconsistency between the terms of any Transition Service Schedule and the terms of this Agreement, the terms of such Transition Service Schedule shall govern.

2.2. Performance of Services. Service Provider will perform the Services set forth in the Transition Service Schedules and all Additional Services.

2.3. Information. Each Transition Service Schedule sets forth, among other things:

2.3.1. a description of the Services to be provided;

2.3.2. the term during which each Service will be provided (the "Service Term");

2.3.3. the location(s) where Services are to be provided;

2.3.4. the Service Provider and Service Recipient Representative(s) for such Service;

2.3.5. the maximum percentage of the applicable Service Provider Representative's working time to be allocated to the Services, based upon a normal 40-hour work week; provided that such maximum will not limit Service Provider's obligation to allocate resources necessary for the performance of any Service in accordance with this Agreement;

2.3.6. the monthly fees due to Service Provider, if any, for each Service; and

2.3.7. any other terms applicable thereto on the Transition Service Schedule.

2.4. Service Levels. Service Provider will perform the Services in a manner consistent with the terms and conditions contained herein and in accordance with applicable Legal Requirements. In addition, in performing the Services, Service Provider will use a degree of care and diligence that is not materially less than the care and diligence exercised by Service Provider and its Affiliates when engaged in similar services or activities during the twelve (12) month period preceding the Execution Date with respect to the Business, and will use commercially reasonable efforts to deliver the Services in a manner consistent with Service Provider's and its Affiliates' past practices. Service Provider will use qualified Service Provider Representatives to perform the Services.

2.5. Additional Resources. Except as provided in a Transition Service Schedule for a specific Service, in providing the Services, Service Provider will not be obligated to:

2.5.1. hire any additional employees;

2.5.2. maintain the employment of any specific employee;

2.5.3. purchase, lease or license any additional equipment or software; or

2.5.4. pay any costs related to the transfer or conversion of Service Recipient's data to Service Recipient or any alternate supplier of Services.

2.6. Additional Services. During the Term, the Parties may identify additional services that Service Provider will provide to Service Recipient in accordance with the terms of this Agreement (the "Additional Services"). Upon mutual agreement of the Parties, the Parties will execute additional written Transition Service Schedules for such Additional Services. Service Provider will have no obligation to execute any additional Transition Service Schedules; provided, that with respect to any Additional Service that has historically been provided by Service Provider or its Affiliates to the Business, Service

Provider will not unreasonably withhold, condition or delay the execution of a Transition Service Schedule relating to such Additional Service to the extent generally consistent with this Agreement, including the Transition Service Schedules.

2.7. Change Order Process. Any change in the scope or duration of any Service described in or other amendment to a Transition Service Schedule must be in writing and signed by the Parties.

2.8. Third-Party Consents. If any consent or waiver from any Third Party is needed in connection with Service Provider's provision of the Services, Service Provider will be excused from performing such Service until such consent or waiver is obtained and will use commercially reasonable efforts to cooperate with Service Recipient to obtain such licenses or approvals, provided that any payments to Third Parties in connection with obtaining any such consent or waiver will be paid by Service Recipient.

ARTICLE 3
GOVERNANCE

3.1. Service Provider Manager and Service Provider Representatives. Service Provider will appoint one individual to have primary responsibility and oversight for the provision of all of the Services by Service Provider and to be Service Recipient's primary point of contact (the "Service Provider Manager"). The initial Service Provider Manager will be Geary MacQuiddy. In addition, Service Provider will identify on the applicable Transition Service Schedule one representative (the "Service Provider Representative") for each Service to have primary responsibility and oversight for the provision or coordination of such Service. Service Provider may appoint a new Service Provider Manager or a new Service Provider Representative for any Service by providing Service Recipient with written notice thereof.

3.2. Service Recipient Manager and Service Recipient Representatives. Service Recipient will appoint one individual to have primary responsibility and oversight for the receipt of all of the Services by Service Recipient and to be Service Provider's primary point of contact (the "Service Recipient Manager"). The initial Service Recipient Manager will be Ross Turbo. In addition, Service Recipient will identify on the applicable Transition Service Schedule one representative (the "Service Recipient Representative") for each Service to have primary responsibility

and oversight for the provision or coordination of such Service. Service Recipient may appoint a new Service Recipient Manager or a new Service Recipient Representative for any Service by providing Service Provider with written notice thereof.

3.3. Dispute Resolution. Any dispute regarding a Party's performance under this Agreement (a "Dispute") will be initially referred to the Service Provider Manager and the Service Recipient Manager. The Service Provider Manager and the Service Recipient Manager will meet at a mutually acceptable time and place (or by teleconference) promptly after the Dispute has been referred to them, and thereafter as often as they reasonably deem necessary, to exchange relevant information and to attempt to resolve the Dispute. If the Service Provider Manager and the Service Recipient Manager are not

able to resolve the Dispute within thirty (30) days after the Dispute has been referred to them, then either Party may thereafter submit such Dispute to any court as permitted by Section 13.9.

ARTICLE 4
TERM AND TERMINATION

4.1. Term. This Agreement will commence on the Effective Date and remain in effect until the last day that any Service Term in any Transition Service Schedule remains in effect (the "Term"), unless earlier terminated under this ARTICLE 4. With respect to each Service, such Service will begin upon the applicable start date set forth in the Transition Services Schedule (or the Effective Date if no start date is identified) and will continue for the longest duration, or until the end date, for such Services set forth in the Transition Services Schedule, unless earlier terminated under this ARTICLE 4. This Agreement may be extended by the Parties in writing, either in whole or with respect to one or more of the Services.

4.2. Termination.

4.2.1. Service Recipient may terminate this Agreement, either with respect to all or with respect to any one or more of the Services (or a portion thereof) provided to Service Recipient hereunder, for any reason or for no reason, at any time upon at least thirty (30) days (or such shorter period to which Service Provider agrees in writing) prior written notice to Service Provider, unless the specific Transition Service Schedule provides otherwise.

4.2.2. Subject to the provisions of ARTICLE 12 below, either Party may terminate this Agreement in its entirety or with respect to affected Services if the other Party materially breaches a material provision with regard to those Services and does not cure such breach, or does not take reasonable steps required under the circumstances to cure such breach going forward, within thirty (30) days (or ten (10) days in the event of a payment breach) after receiving notice of the breach.

4.2.3. Any provision which by its nature or express terms should survive, including the provisions of Section 4.2.4, ARTICLE 5, ARTICLE 10, ARTICLE 11 and ARTICLE 13, will survive the expiration or termination of this Agreement.

4.2.4. Upon any expiration or termination of this Agreement in whole or in part and for any reason (a) each Party will use commercially reasonable efforts to cooperate with the other Party as reasonably necessary to avoid disruption of the ordinary course of the other Party's business and (b) Service Provider will deliver the Data to Service Recipient in accordance with Section 7.4 and will deliver other assets of Service Recipient in the possession of Service Provider. Each Party will promptly return to the other Party or destroy any and all Confidential

Information or other proprietary information of such other Party in its or its Affiliates' possession upon expiration or termination of this Agreement.

ARTICLE 5
PAYMENT TERMS

5.1. Charges for Services. Service Recipient will pay Service Provider the charges, if any, set forth on the applicable Transition Service Schedule for each Service listed therein as adjusted, from time to time, in accordance with Section 5.3.

5.2. Expenses. Service Recipient will, for each Service performed, reimburse Service Provider for any reasonable documented out-of-pocket expenses payable to Third Parties which are incurred by Service Provider or its Affiliates in connection with Service Provider's provision of such Service ("Expenses"); provided that the Expenses will not include the allocation of any corporate overhead or similar expenses incurred by Service Provider or its Affiliates in connection with the performance of the Services. Within ten (10) days after the end of each calendar month during the Term, Service Provider will provide Service Recipient with a report detailing the Expenses for such previous month. In addition, Service Provider will provide Service Recipient with advance written notice of any single Expense or series of related Expenses expected to be in excess of $25,000.

5.3. Payment Terms. Service Provider will bill Service Recipient quarterly for all charges pursuant to this Agreement for the previous calendar quarter. Such invoices will contain reasonable detail of the Services provided and the charge therefor. Service Recipient will pay Service Provider for all undisputed amounts due for Services provided hereunder within thirty (30) days from receipt of an invoice therefor. Late payments will bear interest at the lesser of twelve percent (12%) per annum or the maximum rate allowed by law. The Parties acknowledge and agree that failure to pay undisputed amounts due hereunder pursuant to the terms of this Agreement is a material breach and Service Provider may terminate this Agreement under Section 4.2.

5.4. Disputed Amounts. Amounts due hereunder will not be offset by amounts due under any other agreement. Disputes related to any other agreement will not serve as grounds to delay obligations under this Agreement. In particular, Service Recipient will not, and will cause its Affiliates to not, offset amounts owed to Service Provider or any Affiliate under this Agreement against amounts owed or allegedly owed by Service Provider

or any Affiliate to Service Recipient or any Affiliate under any circumstances, and Service Recipient hereby irrevocably waives any such right on its own behalf and on behalf of each of its Affiliates.

ARTICLE 6
TRANSITION SERVICE RESPONSIBILITIES

6.1. Cooperation; Facilities; Access to Information. The Parties will use good faith efforts to cooperate with each other in all matters relating to the provision and receipt of Services. Such cooperation will include exchanging information relevant to the provision of Services hereunder, good faith efforts to mitigate problems with the work environment

interfering with the Services, and each Party requiring its personnel to obey any security regulations and other published policies of the other Party while on the other Party's premises. In addition, Service Recipient will provide Service Provider with access to its facilities as is reasonably necessary for Service Provider to perform the Services it is obligated to provide hereunder, provide Service Provider with information and documentation reasonably necessary for Service Provider to perform the Services it is obligated to provide hereunder, and make available, as reasonably requested by Service Provider, reasonable access to resources and provide timely decisions in order that Service Provider may perform its obligations hereunder.

6.2. Savings Clause. To the extent Service Recipient's failure to discharge its obligations set forth in Section 6.1 or elsewhere in this Agreement impedes Service Provider's ability to provide any Service or Additional Service hereunder, Service Provider will be excused from its obligation to provide such Services or Additional Services hereunder, provided, that Service Provider provides Service Recipient with notice of Service Recipient's failure to meet such obligation promptly after Service Provider becomes aware of such failure.

ARTICLE 7
INTELLECTUAL PROPERTY

7.1. Existing Ownership Rights Unaffected. Except as expressly set out in this ARTICLE 7, neither Party will gain, by virtue of this Agreement, any rights of ownership or use of Copyrights, Patents, Trade Secrets, Trademarks or any other Intellectual Property owned by the other Party.

7.2. Trademarks. Neither Party is granted hereunder any ownership in or license to the Trademarks of the other Party.

7.3. Removal of Marks. Neither Party will remove any Copyright notices, proprietary markings, Trademarks or other indicia of ownership of the other Party from any materials of the other Party.

7.4. Ownership of Data and Intellectual Property. Service Recipient will own all data and records created by Service Recipient or any of its Affiliates related exclusively to the Business and generated in connection with the performance of the Services (the "Data"). Service Provider will and hereby does, without further consideration, assign (and will cause its Affiliates to assign) to Service Recipient any and all right, title or interest that Service Provider or its Affiliates may possess in or to the Data. Upon Service Recipient's request, Service Provider will provide Service Recipient with copies of the Data in the format in which such Data is generated.

ARTICLE 8
RELATIONSHIP BETWEEN THE PARTIES

8.1. The Parties to this Agreement are and will remain independent contractors and neither Party is an employee, agent, partner, franchisee or joint venturer of or with the other. Each Party will be solely responsible for any employment-related taxes, insurance

premiums or other employment benefits respecting its employees. Neither Party will hold itself out as an agent of the other and neither Party will have the authority to bind the other. (A) No Service Recipient employees, agents or representatives (including the Service Recipient Personnel) shall be eligible to participate in any benefit programs or sales or other bonuses offered by Service Provider to its employees, or in any retirement plans, profit sharing plans, insurance plans, separation plans or any other employee welfare or benefit plans offered from time to time by Service Provider to its employees. Service Recipient acknowledges that none of its employees, agents or representatives (including the Service Recipient Personnel) shall be eligible to participate in, and Service Provider does not and will not maintain or procure for or on such personnel's behalf, any worker's compensation or unemployment compensation insurance. (B) No Service Provider employees, agents or representatives (including the Service Provider Personnel) shall be eligible to participate in any benefit programs or sales or other bonuses offered by Service Recipient to its employees, or in any retirement plans, profit sharing plans, insurance plans, separation plans or any other employee welfare or benefit plans offered from time to time by Service Recipient to its employees. Service Provider acknowledges that none of its employees, agents or representatives (including the Service Provider Personnel) shall be eligible to participate in, and Service Recipient does not and will not maintain or procure for or on such personnel's behalf, any worker's compensation or unemployment compensation insurance.

8.2. (A) Neither the execution of this Agreement, nor performance of Services by the Service Provider and/or any of its Affiliates shall cause the Service Recipient and/or any of its Affiliates or any person or entity employed or engaged by the Service Recipient and/or any of its Affiliates, including the Transferred Employees (collectively "Service Recipient Personnel") to be or to be construed to be an agent, employee or legal representative of the Service Provider and/or any of its Affiliates for any purpose whatsoever. The Service Recipient Personnel shall not be considered to be employees of the Service Provider and/or any of its Affiliates for any purpose (including Section 8.1), and neither the Service Provider nor any of its Affiliates shall be or be deemed to be an employer or joint employer of the Service Recipient Personnel. (B) Neither the execution of this Agreement, nor performance of Services by the Service Provider and/or any of its Affiliates shall cause the Service Provider and/or any of its Affiliates or any person or entity employed or engaged by the Service Provider and/or any of its Affiliates, (collectively "Service Provider Personnel") to be or to be construed to be an agent, employee or legal representative of the Service Recipient and/or any of its Affiliates for any purpose whatsoever. The Service Provider Personnel shall not be considered to be employees of the Service Recipient and/or any of its Affiliates for

any purpose (including Section 8.1), and neither the Service Recipient nor any of its Affiliates shall be or be deemed to be an employer or joint employer of the Service Provider Personnel.

8.3. Notwithstanding anything else in this Agreement and/or the Transition Services Schedule, only members of the Service Recipient Personnel (the "Cleared Service Recipient Personnel") who executed and delivered to the Service Provider an acknowledgment and waiver in the form attached hereto as Schedule 3 may receive, or benefit from, Services that involve access to the information services systems and applications of the Service Provider listed in Schedule 2, and the Service Provider is

under no obligation to provide any such Services to the extent any Service Recipient Personnel other than the Cleared Service Recipient Personnel would receive, or benefit from, such Services.

ARTICLE 9
AFFILIATE PERFORMANCE

Service Provider may engage one or more Affiliates to perform all or any portion of Service Provider's duties under this Agreement; provided that Service Provider remains liable for the performance of such Affiliates.

ARTICLE 10
INDEMNIFICATION

10.1. Service Recipient will indemnify, defend and hold harmless Service Provider and its officers, directors, agents, employees and Affiliates, from and against any and all Damages, including reasonable attorneys' fees (collectively, "Losses") arising out of, relating to or resulting from (a) Service Recipient's material breach of this Agreement, (b) Service Recipient's gross negligence or willful misconduct in connection with its receipt of Services or Additional Services pursuant to this Agreement, (c) Service Recipient Personnel's misuse of any of Service Provider's systems or Services, (d) Service Recipient Personnel's willful misconduct in connection with the use of Service Provider's systems or Services, or (e) Service Provider's provision of Services or Additional Services pursuant to and in accordance with this Agreement, except for those Losses for which Service Provider is obligated to indemnify, defend and hold harmless Service Recipient and its officers, directors, agents, employees and Affiliates pursuant to Section 10.1. Service Recipient will further indemnify, defend and hold harmless Service Provider and its officers, directors, agents, employees and Affiliates, from and against any and all Losses arising out of, relating to or resulting from any Service Recipient Personnel being classified as, or determined to be, co-employed by, or a common-law employee of, the Service Provider and/or any of its Affiliates.

10.2. Service Provider will indemnify, defend and hold harmless Service Recipient and its officers, directors, agents, employees and Affiliates from and against any and all Losses arising out of, relating to or resulting from (a) Service Provider's material breach of this Agreement, (b) Service Provider's gross negligence or willful misconduct in the provision of Services or Additional Services pursuant to this Agreement, (c) any Service Provider Personnel's willful misconduct in connection with providing the Services or Additional Services pursuant to this Agreement, or (d) any Service Provider Personnel's disclosure or misuse of the Service Recipient's Confidential Information. Service Provider will further indemnify, defend and hold harmless Service Recipient and its officers, directors, agents, employees and Affiliates, from and against any and all Losses arising out of, relating to or resulting from any Service Provider Personnel being classified as, or determined to be, co-employed by, or a common-law employee of, the Service Recipient and/or any of its Affiliates.

10.3. An indemnifying Party's indemnification obligations hereunder will be conditioned upon (a) the indemnified Party providing the indemnifying Party with written notice describing such indemnification claim ("Claim") in reasonable detail in light of the circumstances then known and then providing the indemnifying Party with further notices to keep it reasonably informed with respect thereto; provided however, that failure of the indemnified Party to provide such notice or keep the indemnifying Party reasonably informed as provided herein will not relieve the indemnifying Party of its obligations hereunder except to the extent, if any, that the indemnified Party is materially prejudiced thereby, (b) the indemnifying Party being entitled to participate in such Claim and assume the defense thereof with counsel reasonably satisfactory to the indemnified Party, at the indemnifying Party's sole expense, and (c) the indemnified Party reasonably cooperating with the indemnifying Party, at the indemnifying Party's sole cost and expense, in the defense of any Claim. The indemnifying Party will not accept any settlement that places restrictions on any indemnified Party or requires any payment by any indemnified Party and, further, will not accept any settlement unless the settlement includes as an unconditional term thereof the giving by the claimant or the plaintiff of a full and unconditional release of the indemnified Parties, from all liability with respect to the matters that are subject to such Claim, without the indemnified Party's prior written consent, which consent will not be unreasonably withheld, delayed or conditioned. The indemnified Party may participate in the defense of any claim with counsel reasonably acceptable to the indemnifying Party, at the indemnified Party's own expense.

10.4. With the exception of any claims of fraud which are proven and upon which a judgment entered in the involved proceeding will be expressly based, the Parties acknowledge and agree that the provisions of ARTICLE 10 will be the exclusive remedy for all claims relating to this Agreement, including the negotiation or performance hereof.

10.5. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, SERVICE PROVIDER MAKES NO WARRANTY OR REPRESENTATION WHATSOEVER, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR AGAINST INFRINGEMENT.

ARTICLE 11
LIMITATION OF LIABILITY, DISCLAIMER OF CONSEQUENTIAL DAMAGES AND CAP ON LIABILITY

TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LEGAL REQUIREMENTS, AND EXCEPT FOR CLAIMS PURSUANT TO ARTICLE 10 AND IN CIRCUMSTANCES WHERE AWARDED TO A THIRD PARTY, (A) NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR ANY LOST PROFITS OR OTHER SPECIAL, INCIDENTAL, INDIRECT, PUNITIVE OR CONSEQUENTIAL DAMAGES, HOWEVER CAUSED,

UNDER ANY THEORY OF LIABILITY, ARISING FROM THE PERFORMANCE OF, OR RELATING TO, THIS AGREEMENT REGARDLESS OF WHETHER SUCH PARTY HAS BEEN NOTIFIED OF THE POSSIBILITY OF, OR THE FORESEEABILITY OF, SUCH DAMAGES; AND (B) EACH PARTY'S LIABILITY FOR DAMAGES IN CONNECTION WITH THIS AGREEMENT OR THE PERFORMANCE OR NEGOTIATION HEREOF WILL

NOT EXCEED THE AMOUNT OF THE FEES PAID (OR PAYABLE) BY SERVICE RECIPIENT TO SERVICE PROVIDER UNDER THE APPLICABLE TRANSITION SERVICES SCHEDULE FROM WHICH SUCH CLAIM ARISES.

ARTICLE 12
FORCE MAJEURE

Each Party will be excused for any failure or delay in performing any of its obligations under this Agreement, other than the obligations of Service Recipient to make payments to Service Provider for Services already rendered, if such failure or delay is caused by any act of God, any accident, explosion, fire, act of terrorism, storm, earthquake, flood or any other circumstance or event outside of such Party's reasonable control.

ARTICLE 13
MISCELLANEOUS

13.1. Records. Service Provider shall maintain accurate records arising from or related to any Services provided hereunder, including accounting records and documentation produced in connection with the rendering of any Service, substantially consistent with Service Provider's past practices for similar services provided for its own account.

13.2. Inspection Rights. During the Term and for ninety (90) days thereafter, Service Provider shall, upon reasonable prior written notice from Service Recipient, permit Service Recipient, or its designated representatives, to inspect and audit Service Provider's records relating to the Services during regular business hours, with the right to make any copies, for the sole purpose of verifying the amount charged by Service Provider for provision of the Services; provided, that Service Recipient shall comply with Service Provider's reasonable security and safety procedures as such procedures are communicated to Service Recipient.

13.3. SDEA. Within 30 days after the Execution Date but in no event later than the day on which the first Business Permit (i.e., relevant product registration) in respect of any Product will be effectively transferred from the relevant Selling Person to Purchaser in accordance with the Asset Purchase Agreement, the Service Provider (or its relevant Affiliate) and the Service Recipient shall in good faith negotiate and agree in writing a Safety Data and Exchange Agreement ("SDEA"). Such SDEA shall be on terms and conditions customary for similar transactions, and shall govern the transition of pharmacovigilance activities from the relevant Selling Person (and/or its Affiliates) to the Purchaser and the transfer of the safety database at a mutually agreed date. The SDEA shall enable worldwide safety surveillance and risk management and allow each Party to comply with its legal and regulatory obligations as legal manufacturer or holder of the relevant Business Permit (i.e., relevant product registration). The SDEA will be signed by authorized departments of the Parties and shall be considered part of this Agreement, provided however that it can be amended separately without the need to amend this Agreement as a whole.

13.4. Interpretation. Except as otherwise explicitly specified to the contrary, (a) references to a section, exhibit or schedule means a section of, or schedule or exhibit to this Agreement, unless another agreement is specified, (b) the word "including" (in its various forms) means "including without limitation," (c) references to a particular statute or regulation include all rules and regulations thereunder and any predecessor or successor statute, rules or regulation, in each case as amended or otherwise modified from time to time, (d) words in the singular or plural form include the plural and singular form, respectively, (e) references to a particular Person include such Person's successors and assigns to the extent not prohibited by this Agreement, (f) unless otherwise specified "$" is in reference to United States dollars, and (g) the headings contained in this Agreement, in any exhibit or schedule to this Agreement and in the table of contents to this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement.

13.5. Entire Agreement. This Agreement together with the Asset Purchase Agreement and the other Ancillary Agreements, constitutes the entire agreement between and among the Parties with regard to the subject matter of this Agreement, and supersedes all prior agreements and understandings with regard to such subject matter. Except for the Confidentiality Agreement, there are now no agreements, representations or warranties between or among the Parties other than those set forth in the Agreement, the Asset Purchase Agreement or the Ancillary Agreements.

13.6. Amendment, Waivers and Consents. This Agreement may not be changed or modified, in whole or in part, except by supplemental agreement or amendment signed by the Parties. Any Party may waive compliance by any other Party with any of the covenants or conditions of this Agreement, but no waiver will be binding unless executed in writing by the Party making the waiver. No waiver of any provision of this Agreement will be deemed, or will constitute, a waiver of any other provision, whether or not similar, nor will any waiver constitute a continuing waiver. Any consent under this Agreement must be in writing and will be effective only to the extent specifically set forth in such writing.

13.7. Successors and Assigns. This Agreement will bind and inure to the benefit of the Parties and their respective successors and permitted assigns, provided, however, that no Party may assign any right or obligation hereunder without the prior written consent of all other Parties.

13.8. Governing Law. The rights and obligations of the Parties will be governed by, and this Agreement will be interpreted, construed and enforced in accordance with, the laws of the State of New York, excluding its conflict of laws rules to the extent such rules would apply the law of another jurisdiction.

13.9. Jurisdiction; Waiver of Jury Trial.

13.9.1. Any judicial proceeding brought against any Party or any dispute arising out of this Agreement or related to this Agreement, or the negotiation or performance hereof, must be brought in the courts of the State of New York, or in

the U.S. District Court for the State of New York, and, by execution and delivery of this Agreement, each of the Parties accepts the exclusive jurisdiction of such courts, and irrevocably agrees to be bound by any judgment rendered thereby in connection with this Agreement and waives any claim and will not assert that venue should properly lie in any other location within the selected jurisdiction. The consents to jurisdiction in this Section 13.9.1 will not constitute general consents to service of process in the State of New York for any purpose except as provided in this Section 13.9.1 and will not be deemed to confer rights on any Person other than the Parties. Service of any process, summons, notice or document by U.S. mail to a Party's address for notice provided in or in accordance with Section 13.12 will be effective service of process for any action, suit or proceeding in the State of New York with respect to any matters for which it has submitted to jurisdiction pursuant to this Section 13.9.1.

13.9.2. TO THE EXTENT NOT PROHIBITED BY APPLICABLE LAW THAT CANNOT BE WAIVED, THE PARTIES HEREBY WAIVE, AND COVENANT THAT THEY WILL NOT ASSERT (WHETHER AS PLAINTIFF, DEFENDANT OR OTHERWISE), ANY RIGHT TO TRIAL BY JURY IN ANY ACTION ARISING IN WHOLE OR IN PART UNDER OR IN CONNECTION WITH THIS AGREEMENT, WHETHER NOW EXISTING OR HEREAFTER ARISING, AND WHETHER SOUNDING IN CONTRACT, TORT OR OTHERWISE. THE PARTIES AGREE THAT ANY OF THEM MAY FILE A COPY OF THIS PARAGRAPH WITH ANY COURT AS WRITTEN EVIDENCE OF THE KNOWING, VOLUNTARY AND BARGAINED-FOR AGREEMENT AMONG THE PARTIES IRREVOCABLY TO WAIVE ITS RIGHT TO TRIAL BY JURY IN ANY PROCEEDING WHATSOEVER BETWEEN THEM RELATING TO THIS AGREEMENT AND SUCH PROCEEDINGS WILL INSTEAD BE TRIED IN A COURT OF COMPETENT JURISDICTION BY A JUDGE SITTING WITHOUT A JURY.

13.10. Rules of Construction. The Parties acknowledge that each Party has read and negotiated the language used in this Agreement. Because all Parties participated in negotiating and drafting this Agreement, no rule of construction will apply to this Agreement which construes ambiguous language in favor of or against any Party by reason of that Party's role in drafting this Agreement.

13.11. Severability. If any provision of this Agreement, as applied to either Party or to any circumstance, is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement will continue in full force and effect without said provision.

13.12. Notices. Any notice required or permitted to be given hereunder must be provided in writing and (a) delivered in person or by express delivery or courier service, (b) sent by facsimile, or (c) deposited in the mail registered or certified first class, postage prepaid and return receipt requested (provided that any notice given pursuant to subsection (b) of this Section 13.12 is also confirmed by the means described in subsections (a) or (c) of this Section 13.12) to such address or facsimile of the Party set forth in this Section 13.12

or to such other place or places as such Party from time to time may designate in writing in compliance with the terms of this Section 13.12. Each notice will be deemed given when so delivered personally, or sent by facsimile transmission, or, if sent by express delivery or courier service, one Business Day after being sent, or if mailed, five Business Days after the date of deposit in the mail. A notice of change of address or facsimile number will be effective only when done in accordance with this Section 13.12.

(i) To Service Recipient at:

Aastrom Biosciences, Inc.
Domino's Farms, Lobby K
24 Frank Lloyd Wright Drive
Ann Arbor, MI 48105

Attention:	Nick Colangelo
Fax:	+1-734-665-0485
Phone:	+1-734-418-4400

with a copy to:

Goodwin Procter LLP
53 State Street
Exchange Place
Boston, MA 02109

Attention:	Mitchell S. Bloom, Esq. Danielle Lauzon, Esq.
Fax:	+1-617-523-1231
Phone:	+1-617-570-1000

(ii) To Service Provider at:

Genzyme Corporation
55 Cambridge Parkway
Cambridge, MA 02142

Attention:	Head of Biosurgery Global GSU
Facsimile:	+1-617-761-8918

with a copy to:

Sanofi
54, rue la Boétie
75008 Paris
France

Attention: General Counsel

Facsimile: +33-1-5377-4303

and

Ropes & Gray LLP
Prudential Tower
800 Boylston Street
Boston, MA 02199-3600

Attention: Christopher Comeau
Facsimile: +1-617-235-0566

13.13. Rights of Parties. Nothing in this Agreement, whether express or implied, is intended to confer any rights or remedies under or by reason of this Agreement on any Persons other than the Parties to it and their respective successors and permitted assigns, nor is anything in this Agreement intended to relieve or discharge the obligation or liability of any Third Party to any Party, nor will any provision give any Third Party any right of subrogation or action over or against any Party.

13.14. Counterparts. This Agreement may be signed in any number of counterparts, including by facsimile copies or by electronic scan copies delivered by email, each of which will be deemed an original, with the same effect as if the signatures were upon the same instrument.

13.15. Confidentiality.

13.15.1. Neither Party shall possess any interest, title, lien or right in any Confidential Information of the other Party that is exchanged pursuant to or in connection with the terms of this Agreement. Each Party agrees not to (i) disclose the Confidential Information of the other Party to any third party or (ii) use the Confidential Information of the other Party except as necessary to perform its obligations under this Agreement, in either case without the express prior written consent of the other Party, and each Party shall be responsible for any breaches of this Section 13.15 by its directors, officers, employees, representatives (including financial advisors, attorneys and accountants) or agents (collectively, the "Representatives").

13.15.2. The term "Confidential Information" will not, however, include information which (i) is or becomes publicly available other than as a result of a disclosure by the Party or such Party's Representatives receiving the Confidential Information in violation of this Agreement; (ii) is or becomes available on a non-confidential basis from a third-party source (other than the party providing, directly or indirectly, its Confidential Information), which, to the best of the knowledge of the Party receiving Confidential Information after due inquiry, is not prohibited from disclosing such information to it by a legal, contractual or fiduciary obligation to the party providing the Confidential Information; or (iii) was independently developed or learned by a party without the use or reference to the other Party's Confidential Information.

13.15.3. Upon or after the termination or expiration of this Agreement pursuant to Section 4.1 and upon the relevant disclosing Party's written request, the applicable receiving Party shall within thirty (30) business days of such request destroy all copies of such disclosing Party's Confidential Information in its possession or in the possession of any of its Representatives. Notwithstanding the foregoing, the receiving Party of such Confidential Information shall be permitted, subject to its continued compliance with the confidentiality and restricted-use obligations specified in this Agreement, (i) to retain all or any portion of such Confidential Information to the extent necessary for the purposes of maintaning its legal file and using the same to defend against any claims or actions threatened or instituted involving such Confidential Information, and (ii) entitled to retain copies of any computer records and files containing such Confidential Information which have been created pursuant to its automatic electronic archiving and back up procedures. If so requested by the relevant disclosing Party, the receiving Party shall confirm in writing that its undertakings relating to the destruction of any such Confidential Information have been complied with.

13.15.4. Notwithstanding the other provisions of this Section 13.15 either Party may disclose any Confidential Information of the other Party to the extent required by applicable Legal Requirements, The Nasdaq Stock Market, GAAP or IFRS or any disclosure made in connection with the enforcement of any right or remedy relating to this Agreement or the Services; provided that any Party that is requested pursuant to, or required by, applicable Legal Requirements, The Nasdaq Stock Market, GAAP or IFRS to disclose any Confidential Information, shall provide the other Party with reasonable prior written notice of such requests or requirement and a reasonable opportunity is afforded to contest the same.

13.15.5. This Section 13.15, and all rights and obligations hereunder, shall expire three (3) years following the later of (i) the expiration or termination of this Agreement in accordance with its terms and (ii) the delivery to Aastrom by Sanofi, Service Provider

or any of their Affiliates of historical safety data and applicable research and development data. Nothing in this Section 13.15 shall be deemed to limit any rights of Sanofi or Aastrom set forth in the Asset Purchase Agreement.

(The remainder of this page has been intentionally left blank.)

IN WITNESS WHEREOF, each of the Parties has caused this Agreement to be executed on its behalf by their respective officers thereunto duly authorized all as of the Execution Date.

AASTROM BIOSCIENCES, INC.

By: /s/ Dominick C. Colangelo
Name: Dominick C. Colangelo
Title: President and CEO

GENZYME CORPORATION

By: /s/ Jerome Delpech
Name: Jerome Delpech
Title: Attorney-in-Fact

TRANSITION SUPPLY AGREEMENT

This Transition Supply Agreement (this "**Agreement**") is dated as of May 30, 2014 (the "**Effective Date**"), by and between **GENZYME CORPORATION**, a Massachusetts corporation ("**GENZYME**"), and **AASTROM BIOSCIENCES, INC.,** a Michigan corporation ("**AASTROM**"). Genzyme and Aastrom are referred to in this Agreement each as a "Party" and collectively as the "Parties."

PREAMBLE AND BACKGROUND

Sanofi, a French Société Anonyme ("**Sanofi**"), as the seller, and AASTROM, as the buyer, have entered into an Asset Purchase Agreement on April 19, 2014 (the "**APA**"), whereby AASTROM has purchased from Sanofi substantially all of the assets constituting the Business (as such term is defined in the APA) under the terms and conditions set forth in the APA; and

Pursuant to the APA, the Sanofi and AASTROM have agreed to enter into a certain number of transitional agreements, including this Agreement, whereby Sanofi, either directly, through one of its Affiliates, or through a third party shall provide to AASTROM, for a limited period of time from the Closing Date (as such term is defined in the APA), certain raw materials necessary for the Business as such raw materials that are listed in Exhibit 1 (hereafter, such raw materials manufactured by GENZYME, the "**Genzyme Raw Materials**", such raw materials manufactured by third parties, the "**Third Party Raw Materials**" and, collectively, the "**Raw Materials**").

Capitalized terms used and not otherwise defined herein shall have the meanings set forth in the APA.

Now, therefore, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

ARTICLE 1 - SCOPE OF THE AGREEMENT

For the duration of the Agreement, GENZYME undertakes to supply AASTROM with the Raw Materials as so requested by AASTROM and AASTROM undertakes to purchase from GENZYME its requirements of Raw Materials as determined in AASTROM'S sole discretion, subject to the terms and conditions herein set forth.

ARTICLE 2 - SUPPLY

The Genzyme Raw Materials delivered hereunder shall be manufactured in accordance with the applicable current Guidelines of Good Manufacturing Practices for Drugs ("cGMP") and other applicable health authority regulations for therapeutic products as applicable to the Genzyme

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Raw Materials. At the time of delivery to AASTROM by Genzyme, the Genzyme Raw Materials shall have a shelf life of at least the time period specified for such Raw Material on Exhibit 1.

ARTICLE 3 - FORECASTS - ORDERS

3.1 Forecasts

In order to enable GENZYME to regularly supply AASTROM with Raw Materials, AASTROM shall, before the fifth (5th) day of each month, provide GENZYME with a rolling forecast of its needs of Raw Materials for the following six (6) months, or until the end of the Term (defined below), broken down by calendar month. The first three (3) months of the forecast shall be binding.

3.2 Orders of Genzyme Raw Materials

AASTROM will order Genzyme Raw Materials directly from GENZYME. AASTROM will order such quantities of Genzyme Raw Materials to be supplied by GENZYME no less than three (3) months before the delivery date specified by AASTROM if such quantities are included in the rolling forecast.

3.3 Orders of Third Party Raw Materials

To the extent permitted under GENZYME's agreements with the third party manufacturers, AASTROM will order Third Party Raw Materials directly from such third party, with such orders to be delivered to the GENZYME warehouse facility. Upon delivery, GENZYME will record the receipt of such orders via the MFGPro platform. Upon recording the receipt of such orders, AASTROM will have forty-five (45) business days to inspect the Third Party Raw Materials, pursuant to Section 5.2.1. Unless the Third Party Raw Materials are rejected pursuant to Secion 5.2.1, GENZYME will warehouse the Third Party Raw Materials and will fill AASTROM's orders of Third Party Raw Materials upon request for delivery, pursuant to Section 3.4. Upon delivery of the Third Party Raw Materials to AASTROM, AASTROM will perform a further inspection of the Third Party Raw Materials pursuant to Section 5.2.2. Notwithstanding anything to the contrary contained in this Agreement, nothing contained in this Agreement shall require GENZYME to take any actions that would reasonably be expected to result in a breach of any of its existing third party agreements.

3.4 General Provisions

GENZYME will supply the quantities ordered by AASTROM for a given calendar month, provided that such orders do not exceed the forecast quantities for such calendar month, in which case GENZYME will use commercially reasonable efforts to meet AASTROM's needs within a practical time. Notwithstanding the foregoing, it is understood that GENZYME shall not be obliged to deliver any quantities of Raw Materials in excess of the forecast quantities.

Under no circumstances shall GENZYME be obliged to accept any orders in quantities smaller than the minimum order size as reflected in Exhibit 1, or to deliver Raw Materials pursuant to such orders that are smaller than the minimum order size as reflected in Exhibit 1.

Within fifteen (15) working days of receipt of AASTROM's orders of Genzyme Raw Materials pursuant to Section 3.2, or AASTROM's requests for delivery of Third Party Raw Materials pursuant to Section 3.3, GENZYME will acknowledge receipt of each order and either accept such order by confirming that it will deliver the order on the delivery date requested by AASTROM or propose another reasonable delivery date to AASTROM. If AASTROM confirms that such revised delivery date is acceptable to it within five (5) working days of GENZYME's proposal, such order will be deemed accepted for such confirmed delivery date.

If GENZYME is unable to supply Raw Materials to AASTROM in accordance with the quantity or the delivery date specified in any accepted order, GENZYME shall inform AASTROM immediately and the Parties shall agree on an appropriate delivery date and/or other appropriate measures. In the event AASTROM obtains Raw Materials from another source due to a delay exceeding three (3) months, then any raw materials obtained will reduce the binding portion of the forecast accordingly. To the extent such delay is caused exclusively by GENZYME, GENZYME will reimburse AASTROM for all fully documented direct costs and expenses incurred byAASTROM in manufacturing or purchasing replacement Raw Materials that were subject to the purchase order.

ARTICLE 4 - STORAGE

GENZYME shall maintain all stocks of Raw Materials in accordance with cGMP until delivery of such Raw Materials to AASTROM in accordance with this Agreement.

ARTICLE 5 - QUALITY — CONTROL

5.1 Genzyme Raw Materials

5.1.1 The Genzyme Raw Materials delivered by GENZYME hereunder shall be in conformance with the specifications, as specified in Exhibit 1 (hereinafter referred to as the "**SPECIFICATIONS**") at the time of delivery. Each delivery of Genzyme Raw Materials by GENZYME shall be accompanied by a certificate of analysis issued by GENZYME showing the conformity of the delivered batch of Genzyme Raw Materials with the SPECIFICATIONS. Such certificate of analysis shall conform with and be signed in accordance with cGMP and the other applicable regulatory requirements.

5.1.2 AASTROM or its designee shall immediately, upon a shipment's arrival on its site, carefully inspect such shipment of Genzyme Raw Materials for transport damages, losses and shortfalls. AASTROM shall notify the carrier of any apparent defects, including damaged containers or missing packages of Genzyme Raw Materials, within ten business days of arrival of the shipment and the freight documents at AASTROM or its designee's site and, where possible, obtain the countersignature of the carrier's representative. Failure of AASTROM or its designee to notify the carrier of such apparent defects within such period shall excuse GENZYME from any liability with respect to such defects.

5.1.3 AASTROM undertakes to check GENZYME's certificates of analysis for the Genzyme Raw Materials against the SPECIFICATIONS and will test any shipment of Genzyme Raw Materials for identity and compliance with the SPECIFICATIONS.

In the event that any shipment of Genzyme Raw Materials fails to conform with the SPECIFICATIONS, AASTROM shall notify GENZYME thereof within forty-five (45) days of the delivery of Genzyme Raw Materials to AASTROM.

If so requested by GENZYME, AASTROM shall send to GENZYME a sample of the rejected shipment.

At GENZYME's discretion, the batches of Genzyme Raw Materials which do not conform with the SPECIFICATIONS shall either be returned to GENZYME, with freight and insurance charges to be borne by GENZYME, or destroyed by AASTROM, at GENZYME's expense. In such latter case, AASTROM shall give GENZYME evidence of such destruction.

GENZYME's sole obligation and AASTROM's sole and exclusive remedy with respect to such non-conforming Genzyme Raw Materials shall be for GENZYME to replace such Genzyme Raw Materials at no charge to AASTROM as soon as reasonably possible.

5.1.4 Failure of AASTROM to mail notice of rejection within thirty (30) days of the delivery of Genzyme Raw Materials to AASTROM or its designee, as applicable, shall constitute an irrevocable acceptance of such Raw Materials. Notwithstanding anything to the contrary in this Agreement, if defect in the Genzyme Raw Materials could not reasonably be discovered within such thirty (30) day period outlined above (a "Latent Defect"), then AASTROM shall have the right to reject such Genzyme Raw Materials within five (5) calendar days after discovering such Latent Defect, but in any event no later than the shorter of (i) two (2) months from the delivery date of such Genzyme Raw Materials, or (ii) the shelf life of such Genzyme Raw Materials as listed on Exhibit 1.

Any dispute between the Parties regarding the conformity or non-conformity of the Genzyme Raw Materials to the SPECIFICATIONS shall be submitted to an independent laboratory, to be agreed upon by the Parties.

Should the Parties fail to agree on the designation of the independent laboratory within thirty (30) working days of the date that such dispute arises, either Party may seek redress in a court of competent jurisdiction in accordance with the provisions of Article 13.

The decision of such independent laboratory shall be binding on both parties. Any costs or expenses incurred in connection with the dispute resolution by such independent laboratory shall be borne by the non-prevailing Party.

5.1.5 GENZYME makes no warranty of any kind, express or implied, except that the Genzyme Raw Materials sold to AASTROM shall have been manufactured in accordance with Article 2 and shall, upon delivery to AASTROM, conform to the SPECIFICATIONS.

5.2 Third Party Raw Materials

5.2.1 In accordance with Section 3.3, upon arrival of a delivery of Third Party Raw Materials at the GENZYME warehouse facility, AASTROM shall be responsible for

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inspection of such Third Party Raw Materials, including checking any third party manufacturer certificates of analysis against the relevant third party manufacturer specifications or testing any shipment of Third Party Raw Materials for identity and compliance with such specifications. To the extent the Third Party Raw Materials do not conform with the relevant third party manufacturer specifications, the Parties shall cooperate to cause such non-conforming Third Party Materials to be returned to the third party manufacturer according to the procedures prescribed by the underlying agreements with such third party manufacturer.

GENZYME's sole obligation and AASTROM's sole and exclusive remedy with respect to such non-conforming Third Party Raw Materials shall be for GENZYME to cooperate with AASTROM to seek replacement pursuant to the underlying agreements with such third party manufacturers.

5.2.2 Upon final delivery of Third Party Raw Materials from the GENZYME warehouse facility to AASTROM in accordance with Section 3.3, AASTROM or its designee shall immediately inspect such shipment of Third Party Raw Materials for transport damages, losses and shortfalls. AASTROM shall notify the carrier of any apparent defects, including damaged containers or missing packages of Third Party Raw Materials (but excluding defects governed by Section 5.2.1), within ten business days of arrival of the shipment and the freight documents at AASTROM or its designee's site and, where possible, obtain the countersignature of the carrier's representative. Failure of AASTROM or its designee to notify the carrier of such apparent defects within such period shall excuse GENZYME from any liability with respect to such defects.

GENZYME's sole obligation and AASTROM's sole and exclusive remedy with respect to such defective Third Party Raw Materials, where said defects were caused by GENZYME, shall be for GENZYME to replace such Third Party Raw Materials at no charge to AASTROM.

5.2.3 All Third Party Raw Materials supplied by GENZYME to AASTROM pursuant to this Agreement are provided on an "as-is" basis at the sole risk of AASTROM, and GENZYME makes no warranties, express or implied, with respect to any Third Party Raw Materials. Notwithstanding the foregoing, Genzyme will make commercially reasonable efforts to ensure that any express or implied warranties running from any third party manufacturer of Third Party Raw Materials to GENZYME shall also run to the benefit of AASTROM, and such warranties, if any, shall be the sole warranties arising from the supply by GENZYME of Third Party Raw Materials to AASTROM under this Agreement..

5.3 General Provisions

EXCEPT AS EXPRESSLY SET FORTH IN THIS SECTION 5.5, GENZYME MAKES NO WARRANTY, EXPRESS OR IMPLIED, WITH RESPECT TO THE RAW MATERIALS OR ANY PHARMACEUTICAL PRODUCTS PRODUCED FROM OR CONTAINING THE RAW MATERIALS AND EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR OF NON-INFRINGEMENT.

ARTICLE 6 - REGULATORY

6.1 GENZYME shall diligently, at its cost, compile, submit and, at all times during the term of this Agreement, maintain all regulatory filings for the Genzyme Raw Materials in accordance with the standards required by the applicable regulatory authority in the United States.

6.2 GENZYME shall, at its cost, maintain all governmental, regulatory and other licences, consents, approvals and authorisations necessary to ensure the supply, without break in continuity, of Genzyme Raw Materials to AASTROM during the term of this Agreement.

6.3 GENZYME shall provide access at all times to applicable regulatory authorities and co-operate fully with such authorities with respect to any matter involving the Genzyme Raw Materials supplied to AASTROM, or with respect to the warehousing and storage of the Third Party Raw Materials supplied to AASTROM.

AASTROM will be allowed, at any time during the term of the Agreement, to carry out reasonable quality assurance audits of the premises and facilities where the Genzyme Raw Materials are manufactured by GENZYME or any of its Affiliates and to inspect any documentation relating to the quality of the Genzyme Raw Materials, during working hours and with reasonable prior notice to GENZYME.

Where any audit or inspection by the regulatory authorities or representatives of AASTROM identifies any issues that may affect the quality of the Genzyme Raw Materials, such as non-compliance with the applicable cGMP or other legal or regulatory requirements, such issues shall be resolved in accordance with the governance and dispute resolution provisions of Article 3 of the Transition Services Agreement.

6.4 GENZYME shall retain all manufacturing records relating to Genzyme Raw Materials purchased by AASTROM, and retention samples of all Genzyme Raw Materials purchased by AASTROM, for a period of not less than six (6) years.

6.5 GENZYME shall retain exclusive responsibility for all decisions and actions with respect to any complaint, recall, market withdrawal or other corrective action with respect to any products created from or incorporating the Raw Materials until the transfer to AASTROM of the licenses with respect to such products, at which point all such responsibility will transfer to AASTROM.

ARTICLE 7 - PRICES - TERMS OF PAYMENT AND DELIVERY

7.1 The purchase price for Raw Materials shall be: (i) with respect to Third Party Raw Materials, GENZYME's cost of procuring the Third Party Raw Materials plus five percent (the "**Third Party Payment Amount**"), and (ii) with respect to Genzyme Raw Materials, GENZYME's cost of producing the Genzyme Raw Materials as set forth on Exhibit 1 plus five percent (the "**Genzyme Payment Amount**").

Title to a given shipment of Raw Materials shall pass to AASTROM upon full payment of the Third Party Payment Amount or the Genzyme Payment Amount, as applicable, for such shipment.

Notwithstanding the retention of title, transfer of risk with respect to a given shipment of the Raw Materials shall occur upon delivery of such shipment to AASTROM or its designee's site.

7.2 GENZYME shall invoice AASTROM upon delivery of the Raw Materials. Payment shall be due and payable by bank transfer in USD (US Dollars) within thirty (30) days from the date of invoice.

In the absence of the express written consent of GENZYME, failure to pay all or any part of an invoice when due will, without notice and without prejudice to other remedies, automatically give rise to interest for late payment (which may be increased by VAT) which rate shall be equal to the lesser of twelve percent (12%) per annum or the maximum rate allowed by applicable law. Interest shall accrue starting from the initial payment due date until the date of full payment of the applicable invoice.

ARTICLE 8 - LIABILITY - INSURANCE - INDEMNITY

8.1 AASTROM shall assume, upon delivery of any shipment of Raw Materials according to Section 7.1, all risks and liabilities resulting from the storage or any subsequent uses of such shipment of Raw Materials, including in combination with other components, provided that, with respect to Genzyme Raw Materials, at the time of delivery such Genzyme Raw Materials are in compliance with the SPECIFICATIONS and otherwise in accordance with the provisions of this Agreement. GENZYME shall not be responsible for non-conforming Third Party Raw Materials, unless such Third Party Raw Materials are damaged while in GENZYME's possession.

8.2 **TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LEGAL REQUIREMENTS, AND EXCEPT FOR CLAIMS PURSUANT TO SECTIONS 8.5, 8.6 AND 8.7 AND IN CIRCUMSTANCES WHERE AWARDED TO A THIRD PARTY, (A) NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR ANY LOST PROFITS OR OTHER SPECIAL, INCIDENTAL, INDIRECT, PUNITIVE OR CONSEQUENTIAL DAMAGES, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY, ARISING FROM THE PERFORMANCE OF, OR RELATING TO, THIS AGREEMENT REGARDLESS OF WHETHER SUCH PARTY HAS BEEN NOTIFIED OF THE POSSIBILITY OF, OR THE FORESEEABILITY OF, SUCH DAMAGES; AND (B) EACH PARTY'S LIABILITY FOR DAMAGES IN CONNECTION WITH THIS AGREEMENT OR THE PERFORMANCE OR NEGOTIATION HEREOF WILL NOT EXCEED THE AMOUNT OF THE INVOICE FOR THE SHIPMENT OF RAW MATERIALS WITH RESPECT TO WHICH SUCH LOSSES, DAMAGES, LIABILITIES OR EXPENSES AROSE.**

8.3 Each Party shall take all necessary steps, at its own cost and its own behalf to properly insure, with a reputable insurance company as far as reasonably possible, its entire legal liability resulting from its activity performed pursuant to this Agreement.

8.4 Each Party shall promptly inform the other Party of any significant claims or threatened claims in connection with the Raw Materials and shall consult with the other Party with respect to such claims or threatened claims.

8.5 AASTROM will indemnify, defend and hold harmless GENZYME and its officers, directors, agents, employees and Affiliates, from and against any and all Damages,

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including reasonable attorneys' fees (collectively, "**Losses**") arising out of, relating to or resulting from (a) AASTROM's material breach of this Agreement, (b) AASTROM's gross negligence or willful misconduct in connection with its receipt of Raw Materials pursuant to this Agreement or (c) AASTROM's use or GENZYME's provision of Raw Materials supplied pursuant to this Agreement, except for those Losses for which GENZYME is obligated to indemnify, defend and hold harmless Service Recipient and its officers, directors, agents, employees and Affiliates pursuant to Section 8.6.

8.6 GENZYME will indemnify, defend and hold harmless AASTROM and its officers, directors, agents, employees and Affiliates from and against any and all Losses arising out of, relating to or resulting from (a) GENZYME's material breach of this Agreement or (b) GENZYME's gross negligence or willful misconduct in the provision of Genzyme Raw Materials pursuant to this Agreement.

8.7 An indemnifying Party's indemnification obligations hereunder will be conditioned upon (a) the indemnified Party providing the indemnifying Party with written notice describing such indemnification claim ("**Claim**") in reasonable detail in light of the circumstances then known and then providing the indemnifying Party with further notices to keep it reasonably informed with respect thereto; provided however, that failure of the indemnified Party to provide such notice or keep the indemnifying Party reasonably informed as provided herein will not relieve the indemnifying Party of its obligations hereunder except to the extent, if any, that the indemnified Party is materially prejudiced thereby, (b) the indemnifying Party being entitled to participate in such Claim and assume the defense thereof with counsel reasonably satisfactory to the indemnified Party, at the indemnifying Party's sole expense, and (c) the indemnified Party reasonably cooperating with the indemnifying Party, at the indemnifying Party's sole cost and expense, in the defense of any Claim. The indemnifying Party will not accept any settlement that places restrictions on any indemnified Party or requires any payment by any indemnified Party and, further, will not accept any settlement unless the settlement includes as an unconditional term thereof the giving by the claimant or the plaintiff of a full and unconditional release of the indemnified Parties, from all liability with respect to the matters that are subject to such Claim, without the indemnified Party's prior written consent, which consent will not be unreasonably withheld, delayed or conditioned. The indemnified Party may participate in the defense of any claim with counsel reasonably acceptable to the indemnifying Party, at the indemnified Party's own expense.

8.8 With the exception of any claims of fraud which are proven and upon which a judgment entered in the involved proceeding will be expressly based, the Parties acknowledge and agree that the provisions of Sections 8.5, 8.6 and 8.7 will be the exclusive remedy for all claims relating to this Agreement, including the negotiation or performance hereof.

ARTICLE 9 — CONFIDENTIALITY AND INTELLECTUAL PROPERTY

9.1 The Parties may from time to time disclose to each other Confidential Information (as defined in the APA). For avoidance of doubt, the Specifications and batch records, orders and purchasing terms of Aastrom shall be deemed the Confidential Information of Aastrom. Each Party and its Affiliates, shall not disclose such information to third Persons and shall not use such information for purposes other than the purposes expressly set forth in this Agreement, without the prior written consent of the other

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Party. Each Party may disclose such information on a strict need-to-know basis only to Persons directly engaged with such Party's activities under this Agreement (including any Party's Affiliates and their employees), and shall ensure that such Persons are bound by confidentiality obligations equivalent to those set forth in this Agreement. The obligation of confidentiality set forth in this Section 9.1 shall apply during the term of the Agreement and ten (10) years after its termination or expiration.

9.2 The foregoing obligations shall not apply, however, to any part of such information received, which:

a. can be shown by written documentation to have been known to the receiving Party and/or any of its Affiliates prior to disclosure by the disclosing Party, other than such Confidential Information in the possession of Sanofi, GENZYME and their respective Affiliates due to its previous ownership of the Business and/or the Transferred Assets; or

b. was known to the public or generally available to the public prior to the date of the disclosure to the receiving Party by the disclosing Party; or

c. enters the public domain by publication or otherwise through no breach of this Agreement; or

d. can be shown by written documentation to have been made known to the receiving Party and/or any of its Affiliates without breach of any obligation of confidentiality by a third party having the bona fide right to disclose or make available such information.

9.3 Each Party may disclose the confidential information if such disclosure is required by applicable law, regulation or legal process, provided that prior notification of such disclosure is given to to the other Party. In such case, the receiving Party shall promptly notify the other Party in writing and, upon such Party's request (and at the disclosing Party's cost), the receiving Party will reasonably cooperate with the other Party in taking all lawful action (at such other Party's cost) against such compelled disclosure or necessary to comply with such compelled disclosure, as applicable, provided always that any disclosure shall be only to the extent required.

9.4 If GENZYME becomes aware of any infringement of AASTROM's intellectual or industrial property rights related to the Raw Materials by third parties, GENZYME shall immediately notify AASTROM thereof in writing. If reasonably requested by AASTROM, GENZYME will assist or join AASTROM, at AASTROM's expense, in taking such steps as AASTROM and/or its counsel may deem advisable for the protection of AASTROM's rights. The commencement, strategies, termination and settlement of any action relating to the validity or infringement of such property rights shall be decided by AASTROM in its sole discretion. Any such proceedings shall be at the expense of AASTROM and any recoveries shall be for the benefit of AASTROM. Nothing herein, however, shall be deemed to require AASTROM to enforce its property rights against others or to allow AASTROM or require GENZYME to compromise or prejudice any intellectual or industrial property rights belonging to GENZYME or licensed to GENZYME by any third party.

9.5 AASTROM and/or its Affiliates, as the case may be, retain all rights, title and interest in and to the technical information and any other industrial and/or intellectual property rights related to the Raw Materials.

ARTICLE 10 - FORCE MAJEURE

10.1 Each Party will be excused for any failure or delay in performing any of its obligations under this Agreement, other than the obligations of AASTROM to make payments to GENZYME for shipments of Raw Materials, if such failure or delay is caused by any act of God, any accident, explosion, fire, act of terrorism, storm, earthquake, flood, failure of common carrier, failure of third party manufacturer, strike, work stoppage, shortage of any raw materials or any components or any other circumstance or event outside of such Party's reasonable control (a "**Force Majeure**").

10.2 The Party asserting Force Majeure shall promptly notify the other Party of the event constituting Force Majeure and of all relevant details, and shall furnish appropriate evidence of the occurrence.

10.3 Thereafter, the Parties shall consult with each other in order to find a fair solution and shall use commercially reasonable efforts to minimise the consequences of such Force Majeure.

10.4 Notwithstanding anything to the contrary, either Party shall have the right to terminate this Agreement upon thirty (30) days' prior written notice to the other Party if the inability of such other Party to fulfil its obligations due to Force Majeure exceeds a three (3)-month period.

10.5 If the Parties are unable to agree that an event of Force Majeure has occurred, the matter shall be settled in accordance with the dispute resolution provisions set forth in Article 14 of this Agreement.

ARTICLE 11 - TERM AND TERMINATION

11.1 This Agreement and all of its terms and conditions shall become effective as of the Effective Date and shall remain in full force for a maximum period of twelve (12) months (the "**Term**").

11.2 Either Party may terminate this Agreement at any time during the Term, effective immediately, upon written notice to the other Party:

(i) if the other Party commits a breach under this Agreement and fails, within thirty (30) days of receipt of written notice of such breach (or ten (10) days in the event of a payment breach), (x) to remedy the same (if capable of remedy) or (y) if the breach is one which requires more than thirty (30) days to cure, to commence without delay and diligently pursue the remedy within such time;

(ii) if the other Party goes into bankruptcy or insolvency or is liquidated (other than for the purposes of a bona fide corporate reorganization or amalgamation); or

(iii) in the cases expressly provided for in Section 10.4.

11.3 GENZYME shall be entitled to terminate the Agreement immediately (i) with respect to any Third Party Raw Materials, in the event that the third party agreements governing the supply of those materials are terminated; provided that GENZYME shall have informed AASTROM in advance with respect to the proposed termination of such third party agreements, or (ii) in the event of a breach by AASTROM of the terms of Section 12.2 (Anti-Bribery), without payment of any compensation or other damages to AASTROM arising out of such termination (regardless of any activities or agreements with any third parties entered into by AASTROM prior to the termination of this Agreement) by giving notice in writing to AASTROM. GENZYME will not be liable for, nor make any payment to AASTROM in respect of, any direct economic loss or other loss of turnover, profits, business or goodwill or any special, indirect or consequential losses suffered by AASTROM as a result of such termination. The right to terminate this Agreement under this Clause 11.3 will be without prejudice to any other right or remedy of GENZYME which may have accrued up to the date of termination. AASTROM shall be entitled to terminate the Agreement immediately in the event of a breach by GENZYME of the terms of Section 12.2 (Anti-Bribery), without payment of any compensation or other damages to GENZYME arising out of such termination (regardless of any activities or agreements with any third parties entered into by GENZYME prior to the termination of this Agreement) by giving notice in writing to GENZYME. AASTROM will not be liable for, nor make any payment to GENZYME in respect of, any direct economic loss or other loss of turnover, profits, business or goodwill or any special, indirect or consequential losses suffered by GENZYME as a result of such termination. The right to terminate this Agreement under this Clause 11.3 will be without prejudice to any other right or remedy of AASTROM which may have accrued up to the date of termination. AASTROM may terminate this Agreement in its entirety, without charge or penalty upon written notice to GENZYME; provided that AASTROM shall remain liable for any undelivered Raw Materials specified in the then-current binding purchase orders for Raw Materials.

11.4 The termination of this Agreement for whatever cause shall neither affect any of the rights or obligations of either Party which have accrued through the effective date of such termination, nor affect any rights or obligations of either Party under this Agreement that are intended by the Parties to survive such expiration or termination.

11.5 The termination of this Agreement for whatever cause shall not excuse AASTROM from the payment to GENZYME of any amounts due for shipments of Raw Materials already delivered or from the reimbursement of GENZYME for any non-cancellable costs incurred in connection with the manufacture or sourcing of the Raw Materials through the effective date of such termination.

11.6 Any provision which by its nature should survive, including the provisions of Section 11.7, Article 7, Article 8, and Article 12, will survive the expiration or termination of this Agreement.

11.7 Upon any expiration or termination of this Agreement in whole or in part and for any reason (a) each Party will use commercially reasonable efforts to cooperate with the other Party as reasonably necessary to avoid disruption of the ordinary course of the other Party's business and (b) each Party will promptly return to the other Party or destroy any and all confidential information or other proprietary information of such

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other Party in its or its Affiliates' possession upon expiration or termination of this Agreement.

ARTICLE 12 - MISCELLANEOUS

12.1 Hardship

Should any unforeseen event, while not preventing either Party from performing any of its obligations hereunder, cause either Party inequitable hardship with respect to the performance of such obligations, and the Party can demonstrate this by competent proof, then both Parties shall negotiate in good faith an equitable way to adapt this Agreement to the new circumstances.

12.2 Anti-Bribery

Each Party warrants, represents and undertakes that (a) it will comply with the requirements of all applicable anti-bribery legislation, both national and foreign, including but not limited to the OECD Convention dated 17th December 1997 on combating bribery of public officials in international business, and (b) it has not and will not make, promise or offer to make any payment or transfer anything of value (directly or indirectly) to (i) any individual, (ii) corporation, (iii) association, (iv) partnership or (v) public body (including but not limited to any officer or employee of any of the foregoing) who, acting in their official capacity or of their own accord, are in a position to influence, secure or retain any business for (and/or provide any financial or other advantage to) the other Party by improperly performing a function of a public nature or a business activity with the purpose or effect of public or commercial bribery, acceptance of or acquiescence in extortion, kickbacks or other unlawful or improper means of obtaining or retaining business.

Each Party will immediately notify the other Party if, at any time during the term of this Agreement, its circumstances, knowledge or awareness change such that it would not be able to repeat the warranties set forth above at such time.

Each Party undertakes throughout the term of this Agreement to keep detailed and up-to-date books of account and records of all acts by it in relation to this Agreement for a minimum period of seven (7) years and, at the other Party's request, to make them available for inspection. Without prejudice

to the generality of the foregoing, this obligation will extend to records of all payments made by AASTROM in connection with this Agreement. Each Party will ensure that such books of account and records are sufficient to enable the other Party to verify compliance with this Section 12.2.

12.3 Records

GENZYME shall maintain accurate records arising from or related to any Raw Materials supplied hereunder, including accounting records and documentation produced in connection with the supply of any Raw Materials, substantially consistent with GENZYME's past practices for similar supply of materials for its own account.

12.4 Inspection Rights

During the Term and for ninety (90) days thereafter, GENZYME shall, upon reasonable prior written notice from AASTROM, permit AASTROM, or its designated

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representatives, to inspect and audit GENZYME's records relating to the supply of Raw Materials during regular business hours, with the right to make any copies, for the sole purpose of verifying the amount charged by GENZYME for the Raw Materials; provided, that AASTROM shall comply with GENZYME's reasonable security and safety procedures as such procedures are communicated to AASTROM.

12.5 Interpretation

Except as otherwise explicitly specified to the contrary, (a) references to a section, exhibit or schedule means a section of, or schedule or exhibit to this Agreement, unless another agreement is specified, (b) the word "including" (in its various forms) means "including without limitation," (c) references to a particular statute or regulation include all rules and regulations thereunder and any predecessor or successor statute, rules or regulation, in each case as amended or otherwise modified from time to time, (d) words in the singular or plural form include the plural and singular form, respectively, (e) references to a particular Person include such Person's successors and assigns to the extent not prohibited by this Agreement, (f) unless otherwise specified "$" is in reference to United States dollars, and (g) the headings contained in this Agreement, in any exhibit or schedule to this Agreement and in the table of contents to this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement.

12.6 Severability

Any provision of this Agreement which is held to be invalid and unenforceable in any jurisdiction shall be ineffective as to such jurisdiction, without invalidating the remaining provisions hereof or affecting the validity or enforcement of such provision in other jurisdictions, and this Agreement will continue in full force and effect without said provision; provided, however, that if the economic terms of this Agreement are materially altered by such invalidity for one of the Parties, the Parties shall negotiate to modify such invalid clause in such a way as to preserve the financial equilibrium contemplated at the signature of this Agreement.

12.7 Assignment, Sub-contracting and Licensees

This Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns, provided, however, that no Party may assign any right or obligation hereunder, in whole or in part, without the prior written consent of the other Party, which consent may not be unreasonably withheld, provided that GENZYME is entitled to assign any of its rights and/or obligations hereunder to any of its Affiliates, whether presently existing or to be created or acquired in the future, without the prior written approval of AASTROM.

AASTROM acknowledges that GENZYME may use contractors and third parties to manufacture Third Party Raw Materials and supply Third Party Raw Materials to AASTROM under this Agreement. Subject to the provisions of Section 5.5, GENZYME shall have no liability to AASTROM for any acts or omissions of such contractors or third parties.

12.8 Notice

Any notice required or permitted to be given hereunder must be provided in writing and (a) delivered in person or by express delivery or courier service, (b) sent by facsimile, or (c) deposited in the mail registered or certified first class, postage prepaid and return receipt requested (provided that any notice given pursuant to subsection (b) of this Section 12.8 is also confirmed by the means described in subsections (a) or (c) of this Section 12.8) to such address or facsimile of the Party set forth in this Section 12.8 or to such other place or places as such Party from time to time may designate in writing in compliance with the terms of this Section 12.8. Each notice will be deemed given when so delivered personally, or sent by facsimile transmission, or, if sent by express delivery or courier service, one Business Day after being sent, or if mailed, five Business Days after the date of deposit in the mail. A notice of change of address or facsimile number will be effective only when done in accordance with this Section 12.8.

(i) To AASTROM at:

Aastrom Biosciences, Inc.
Domino's Farms, Lobby K
24 Frank Lloyd Wright Drive
Ann Arbor, MI 48105

Attention: Nick Colangelo
Fax: +1-734-665-0485
Phone: +1-734-418-4400

With a copy to:

Goodwin Procter LLP
53 State Street
Exchange Place
Boston, MA 02109

Attention: Mitchell S. Bloom, Esq.
Danielle Lauzon, Esq.
Fax: +1-617-523-1231
Phone: +1-617-570-1000

(ii) To GENZYME at:

Genzyme Corporation
55 Cambridge Parkway
Cambridge, MA 02142

Attention: Head of Biosurgery Global GSU
Fax: +1-617-761-8918

With a copy to:

Sanofi
54, rue la Boétie
75008 Paris, France

Attention: General Counsel

Fax: +33-1-5377-4303

And

Ropes & Gray LLP
Prudential Tower
800 Boylston Street
Boston, MA 02199-0566

Attention: Christopher Comeau
Fax: +1-617-235-0566

12.9 Independent Contractors

The Parties to this Agreement are and will remain independent contractors and neither Party is an employee, agent, partner, franchisee or joint venturer of or with the other. Each Party will be solely responsible for any employment-related taxes, insurance premiums or other employment benefits respecting its employees. Neither Party will hold itself out as an agent of the other and neither Party will have the authority to bind the other.

12.10 Entire Agreement

This Agreement together with the Asset Purchase Agreement and the other Ancillary Agreements, constitutes the entire agreement between and among the Parties with regard to the subject matter of this Agreement, and supersedes all prior agreements and understandings with regard to such subject matter. Except for the Confidentiality Agreement, there are now no agreements, representations or warranties between or among the Parties other than those set forth in this Agreement or the Ancillary Agreements.

The provisions of this Agreement shall prevail over any conflicting or inconsistent terms or conditions contained in any invoices, purchase orders or other documents submitted by either Party to the other Party.

12.11 Amendment, Waivers and Consents

This Agreement may not be changed or modified, in whole or in part, except by supplemental agreement or amendment signed by the Parties. Any Party may waive compliance by any other Party with any of the covenants or conditions of this Agreement, but no waiver will be binding unless executed in writing by the Party making the waiver. No waiver of any provision of this Agreement will be deemed, or will constitute, a waiver of any other provision, whether or not similar, nor will any waiver constitute a continuing waiver. Any consent under this Agreement must be in writing and will be effective only to the extent specifically set forth in such writing.

12.12 Rules of Construction

The Parties acknowledge that each Party has read and negotiated the language used in this Agreement. Because all Parties participated in negotiating and drafting this Agreement, no rule of construction will apply to this Agreement which construes

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ambiguous language in favor of or against any Party by reason of that Party's role in drafting this Agreement.

12.13 Rights of Parties

Nothing in this Agreement, whether express or implied, is intended to confer any rights or remedies under or by reason of this Agreement on any Persons other than the Parties to it and their respective successors and permitted assigns, nor is anything in this Agreement intended to relieve or discharge the obligation or liability of any Third Party to any Party, nor will any provision give any Third Party any right of subrogation or action over or against any Party.

12.14 Counterparts

This Agreement may be signed in any number of counterparts, including by facsimile copies or by electronic scan copies delivered by email, each of which will be deemed an original, with the same effect as if the signatures were upon the same instrument.

ARTICLE 13 — GOVERNING LAW; JURISDICTION; WAIVER OF JURY TRIAL

13.1 This Agreement shall be governed by and construed in accordance with the laws of the State of New York, excluding its conflict of laws rules to the extent such rules would apply the law of another jurisdiction.

13.2 Any judicial proceeding brought against any Party or any dispute arising out of this Agreement or related to this Agreement, or the negotiation or performance hereof, must be brought in the courts of the State of New York, or in the U.S. District Court for the State of New York, and, by execution and delivery of this Agreement, each of the Parties accepts the exclusive jurisdiction of such courts, and irrevocably agrees to be bound by any judgment rendered thereby in connection with this Agreement and waives any claim and will not assert that venue should properly lie in any other location within the selected jurisdiction. The consents to jurisdiction in this Section 13.2 will not constitute general consents to service of process in the State of New York for any purpose except as provided in this Section 13.2 and will not be deemed to confer rights on any Person other than the Parties. Service of any process, summons, notice or document by U.S. mail to a Party's address for notice provided in or in accordance with Section 12.8 will be effective service of process for any action, suit or proceeding in the State of New York with respect to any matters for which it has submitted to jurisdiction pursuant to this Section 13.2

13.3 TO THE EXTENT NOT PROHIBITED BY APPLICABLE LAW THAT CANNOT BE WAIVED, THE PARTIES HEREBY WAIVE, AND COVENANT THAT THEY WILL NOT ASSERT (WHETHER AS PLAINTIFF, DEFENDANT OR OTHERWISE), ANY RIGHT TO TRIAL BY JURY IN ANY ACTION ARISING IN WHOLE OR IN PART UNDER OR IN CONNECTION WITH THIS AGREEMENT, WHETHER NOW EXISTING OR HEREAFTER ARISING, AND WHETHER SOUNDING IN CONTRACT, TORT OR OTHERWISE. THE PARTIES AGREE THAT ANY OF THEM MAY FILE A COPY OF THIS PARAGRAPH WITH ANY COURT AS WRITTEN EVIDENCE OF THE KNOWING, VOLUNTARY AND BARGAINED-FOR AGREEMENT AMONG THE PARTIES IRREVOCABLY TO WAIVE ITS RIGHT TO TRIAL BY JURY IN ANY PROCEEDING WHATSOEVER BETWEEN THEM RELATING TO THIS

AGREEMENT AND SUCH PROCEEDINGS WILL INSTEAD BE TRIED IN A COURT OF COMPETENT JURISDICTION BY A JUDGE SITTING WITHOUT A JURY.

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

GENZYME

By: /s/ Jerome Delpech
Name: Jerome Delpech
Title: Attorney-in-Fact

AASTROM

By: /s/ Dominick C. Colangelo
Name: Dominick C. Colangelo
Title: President and CEO

Exhibit 99.1

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Domino's Farms, Lobby K
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Ann Arbor, MI 48105
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www.aastrom.com

For Immediate Release

Aastrom Completes Acquisition of Sanofi's Cell Therapy and Regenerative Medicine Business

ANN ARBOR, Mich., June 2, 2014 (GLOBE NEWSWIRE) — Aastrom Biosciences, Inc. (Nasdaq: ASTM), the leading developer of patient-specific expanded cellular therapies for the treatment of severe diseases and conditions, today announced that the company has completed its acquisition of Sanofi's cell therapy and regenerative medicine (CTRM) business unit. As announced on April 21, 2014, Aastrom paid $4 million in cash and $2.5 million in a promissory note to acquire the CTRM business, which includes three marketed products in the United States and Europe as well as manufacturing and production centers in the U.S. and Denmark.

The three marketed autologous cell therapy products acquired by Aastrom in this acquisition are Carticel® (autologous cultured chondrocytes), an autologous chondrocyte implant (ACI) product marketed in the United States for the treatment and repair of articular cartilage defects in the knee; Epicel® (cultured epidermal autografts), a permanent skin replacement for full-thickness burns greater than or equal to 30% of total body surface area, which is marketed in the United States; and MACI® (matrix-applied characterized autologous cultured chondrocytes), a third-generation ACI product currently marketed in the European Union for the treatment of focal chondral defects in the knee. Revenues for all three products were $44 million in 2013.

"This acquisition significantly expands our cell therapy product portfolio with proven-effective commercial products and enhances our manufacturing, sales and marketing capabilities," said Nick Colangelo, president and chief executive officer of Aastrom. "We look forward to building upon the record of successful product innovation and customer service of the CTRM business and leveraging the capabilities of the combined organization as we develop our current pipeline, expand our cell therapy business and explore other strategic growth opportunities."

About Aastrom Biosciences

Aastrom Biosciences is the leader in developing patient-specific expanded cellular therapies for use in the treatment of patients with severe diseases and conditions. Aastrom markets three autologous cell therapy products in the United States and European Union for the treatment of cartilage repair and skin replacement, and is developing ixmyelocel-T, a patient-specific multicellular therapy for the treatment of advanced heart failure due to ischemic dilated cardiomyopathy. For more information, please visit Aastrom's website at www.aastrom.com.

The Aastrom Biosciences, Inc. logo is available at
http://www.globenewswire.com/newsroom/prs/?pkgid=3663
http://www.globenewswire.com/newsroom/prs/?pkgid=3663

This document contains forward-looking statements, including, without limitation, statements concerning clinical trial plans and progress, objectives and expectations, clinical activity timing, intended product development, anticipated milestones, potential advantages of our product candidates and the commercial success of our products, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as "anticipates," "intends," "estimates," "plans," "expects," "we believe," "we intend," and similar words or phrases, or future or conditional verbs such as "will," "would," "should," "potential," "could," "may," or similar expressions. Actual results may differ significantly from the expectations contained in the forward-looking statements. Among the factors that may result in differences are the inherent uncertainties associated with the clinical trial and product development activities, regulatory approval requirements, competitive developments, product commercialization and the availability of resources and the allocation of resources among different potential uses. These and other significant factors are discussed in greater detail in Aastrom's Annual Report on Form 10-K for the year ended December 31, 2013, filed with the Securities and Exchange Commission ("SEC") on March 13, 2014, Quarterly Reports on Form 10-Q and other filings with the SEC. These forward-looking statements reflect management's current views and Aastrom does not undertake to update any of these forward-looking statements to reflect a change in its views or events or circumstances that occur after the date of this release except as required by law.

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