
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): **November 14, 2016**

Asterias Biotherapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

001-36646

46-1047971

(State or other jurisdiction of incorporation)

(Commission File Number)

(IRS Employer Identification No.)

**6300 Dumbarton Circle
Fremont, CA 94555**

(Address of principal executive offices)

(510) 456-3800

(Registrant's telephone number, including area code)

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:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02 Results of Operations and Financial Condition.

On November 14, 2016, Asterias Biotherapeutics, Inc. (the “Company”) announced via press release certain operating and financial results for the quarter ended September 30, 2016. A copy of the Company’s press release is attached hereto as Exhibit 99.1.

Also on November 14, 2016, the Company held a conference call with analysts and investors, the transcript is filed as Exhibit 99.2 hereto and is incorporated herein by reference.

In accordance with General Instruction B.2. of Form 8-K, the information in Item 2.02 of this Current Report on Form 8-K, including Exhibits 99.1 and 99.2, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Tables and Exhibits.

(d) Exhibits.

Exhibit

No. Description

[99.1](#) Asterias Biotherapeutics, Inc. Press Release dated November 14, 2016.

[99.2](#) Transcript of conference call held on November 14, 2016.

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.

ASTERIAS BIOTHERAPEUTICS, INC.

Date: November 16, 2016

By: /s/ Ryan D. Chavez
Executive Vice President, Finance and General Counsel



Asterias Biotherapeutics Reports Third Quarter Results and Accelerating Enrollment of AST-OPC1 SCiStar Phase 1/2a Study

-Study enrollment has recently accelerated, with three patients dosed in past week-

-Achievement of enrollment milestone meets requirement for an additional \$2.5 million grant payment to Asterias from the California Institute for Regenerative Medicine-

-SCiStar investigator and patient will discuss experiences with AST-OPC1 on call today at 4:30 p.m. Eastern / 1:30 p.m. Pacific-

FREMONT, Calif. – November 14, 2016 – Asterias Biotherapeutics, Inc. (NYSE MKT: AST), a biotechnology company pioneering the field of regenerative medicine, today reported financial results for the third quarter ended September 30, 2016. In addition, the Company disclosed that there has been a recent acceleration in AST-OPC1 SCiStar study enrollment with three patients having been dosed over the past week. In addition to the previously completed dosing of the 2 million and 10 million cell AIS-A cohorts, Asterias has now treated two AIS-A patients with the maximum dose of 20 million AST-OPC1 cells and two AIS-B patients with 10 million AST-OPC1 cells.

The significant enrollment progress has also met requirements for an additional \$2.5 million grant payment to the company under the Strategic Partnerships Award grant from the California Institute for Regenerative Medicine, which provides \$14.3 million of non-dilutive funding for the Phase 1/2a clinical trial and other product development activities for AST-OPC1.

AIS-A patients are characterized by cervical spinal cord injuries resulting in complete loss of motor and sensory function below the cervical injury site, while AIS-B patients have similar cervical injuries and complete motor loss but retain some sensory function. The company believes AIS-B patients may be particularly responsive to AST-OPC1 due to the larger amount of intact spinal tissue remaining in these patients at the injury site.

“Since mid-September, when we presented promising early data from AIS-A patients dosed with 10 million cells, our clinical team has continued to make excellent progress enrolling additional patients in the SCiStar study,” said Steve Cartt, President and Chief Executive Officer. “We have now dosed two patients each in both the AIS-A 20 million cell cohort and the AIS-B 10 million cell cohort. The early efficacy data presented in September for AST-OPC1 was very encouraging, and we look forward to presenting the six-month efficacy and safety results for this cohort in January 2017. We also look forward to Dr. Kurpad and his patient joining our conference call this afternoon to share their experience with AST-OPC1.”

Asterias management will be joined on the conference call by Shekar N. Kurpad, MD, PhD, Professor of Neurosurgery, Director, Spinal Cord Injury Center Medical College of Wisconsin and a clinical investigator for the SCiStar study. Dr. Kurpad will discuss his experience to date with AST-OPC1 at his institution, and will be joined on the call by one of his patients who received AST-OPC1.

Recent Research and Development Highlights

AST-OPC1 (oligodendrocyte progenitor cells)

- In August, the Data Monitoring Committee (DMC) for the SCiStar clinical study granted clearance to begin dosing a cohort of AIS-A patients with the highest dose of 20 million AST-OPC1 cells. The decision was based on the DMC's independent safety review of data from the 2 million cell and 10 million cell AIS-A cohorts.
 - In September, Asterias presented positive efficacy data from the AIS-A 10 million cell cohort, including the following highlights:
 - The efficacy target of 2 of 5 patients in the cohort achieving two motor levels of improvement on at least one side of their body had already been achieved.
 - At Day 90 of follow up, 4 of 4 patients dosed had improved motor function on at least one side, 2 patients had improved one motor level on at least one side, with one improving two motor levels on one side, and one improving two motor levels on both sides.
 - The average upper extremity motor scores (UEMS) improvement at Day 90 for the 4 patients that had reached this follow up was 9.5 points compared to 5.0 points at Day 90 for patients dosed with 2 million cells, which may also begin to support a dose dependent response.
 - No serious adverse events related to AST-OPC1 have been observed to date.
 - As suggested by existing research, patients with complete cervical spinal cord injuries that show two motor levels of improvement on at least one side may regain the ability to perform daily activities such as feeding, dressing and bathing. Meaningful improvement in motor function, particularly in the use of a patient's hands, fingers and arms, is critically important for a patient's quality of life and ability to function independently. Consistent with their improvements in motor level and UEMS, subjects in the SCiStar study have demonstrated improvements in their ability to independently perform activities of daily living including feeding themselves, drinking, texting, sending emails, and signing their names.
 - In September, Asterias successfully dosed the first AIS-B patient with 10 million AST-OPC1 cells and has since enrolled an additional patient in this cohort. A total of 5-8 patients are expected to be enrolled in this cohort.
 - In November, Asterias successfully dosed the first AIS-A patient with 20 million cells of AST-OPC1, triggering an additional \$2.5 million payment to the company under its Strategic Partnerships Award grant from the California Institute for Regenerative Medicine, and has since enrolled an additional patient in this cohort. A total of 5-8 patients are expected to be enrolled in this cohort.
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AST-VAC1 (antigen-presenting autologous dendritic cells)

- Process development efforts continue on the AST-VAC1 program, in advance of a planned phase 2b trial in Acute Myeloid Leukemia (AML), the most common form of acute leukemia in adults.

AST-VAC2 (antigen-presenting allogeneic dendritic cells)

- Current production scale pilot lots of AST-VAC2 have been successfully manufactured, triggering the initiation of clinical AST-VAC2 lots under current Good Manufacturing Practices (cGMP) conditions in the fourth quarter 2016.
- Preparation of a regulatory dossier to support execution of a phase 1/2a clinical trial of AST-VAC2 in patients with non-small cell lung carcinoma is underway, with submission to the UK Medicines and Healthcare Products Agency (MHRA) planned early in the first quarter of 2017.

Third Quarter Financial Update

Total revenues were \$2.1 million for the third quarter, and \$5.2 million for the nine months ended September 30, 2016. Revenues were comprised of grant income as well as royalty revenues on product sales by licensees. Research and development expenses were \$5.2 million for the third quarter and \$17.6 million for the nine months ended September 30, 2016, with the primary driver being expenses associated with our AST-OPC1 program. General and administrative expenses were \$4.2 million for the third quarter and \$13.1 million for the nine months ended September 30, 2016. Non-cash expenses related to warrants distributed to shareholders earlier in the year and which were included in general and administrative expenses were \$2.1 million for the third quarter and \$5.3 million for the nine months ended September 30, 2016. Net loss was \$10.6 million, or \$0.24 per share, for the third quarter and \$26.1 million, or \$0.63 per share, for the nine months ended September 30, 2016. For the nine months ended September 30, 2016 net cash used in operating activities was \$15.1 million and net cash provided from financing activities was \$22.4 million.

As of September 30, 2016, the company's cash, cash equivalents and available-for-sale securities totaled \$33.9 million, which management believes will be sufficient to fund operations through the third quarter of 2017.

Conference Call and Webcast Details

Asterias will host a conference call and webcast today, November 14, 2016 at 4:30 p.m. Eastern / 1:30 p.m. Pacific to discuss the results and corporate developments. Company management will be joined by Shekar N. Kurpad, MD, PhD, Professor of Neurosurgery, Director, Spinal Cord Injury Center Medical College of Wisconsin and a clinical investigator for the SCiStar study. Dr. Kurpad will discuss his experience to date with AST-OPC1 at his institution, and will be joined on the call by one of his patients who received AST-OPC1. To access a video that includes Dr. Kurpad, other clinical investigators, as well as patients who have been treated with AST-OPC1, please click on the following link: <http://asteriasbiotherapeutics.com/>.

For both “listen-only” participants and those participants who wish to take part in the question-and-answer session, the call can be accessed by dialing 877-719-9799 (U.S./Canada) or 719-325-4838 (international) five minutes prior to the start of the call and providing the Conference ID 5481738. To access the live webcast, go to <http://asteriasbiotherapeutics.com/events-presentations/>.

A replay of the conference call will be available for seven business days beginning about two hours after the conclusion of the live call, by dialing 888-203-1112 (U.S./Canada) or 719-457-0820 (international) and providing the Conference ID 5481738. Additionally, the archived webcast will be available at <http://asteriasbiotherapeutics.com/events-presentations/>.

About Asterias Biotherapeutics

Asterias Biotherapeutics, Inc. is a biotechnology company pioneering the field of regenerative medicine. The company’s proprietary cell therapy programs are based on its immunotherapy and pluripotent stem cell platform technologies. Asterias is presently focused on advancing three clinical-stage programs which have the potential to address areas of very high unmet medical need in the fields of neurology and oncology. AST-OPC1 (oligodendrocyte progenitor cells) is currently in a Phase 1/2a dose escalation clinical trial in spinal cord injury.

AST-VAC1 (antigen-presenting autologous dendritic cells) is undergoing continuing development by Asterias after demonstrating promise in a Phase 2 study in Acute Myeloid Leukemia (AML) and completing a successful end-of-Phase 2 meeting with the FDA. The company is currently focused on streamlining and modernizing the manufacturing process for AST-VAC1 in advance of a planned initiation of a confirmatory phase 2b study. AST-VAC2 (antigen-presenting allogeneic dendritic cells) represents a second generation, allogeneic immunotherapy. The company’s research partner, Cancer Research UK, plans to begin a Phase 1/2a clinical trial of AST-VAC2 in non-small cell lung cancer in the first half of 2017. Additional information about Asterias can be found at www.asteriasbiotherapeutics.com.

Forward Looking Statements

Statements pertaining to future financial and/or operating and/or clinical research results, future growth in research, technology, clinical development, and potential opportunities for Asterias, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management constitute forward-looking statements. Any statements that are not historical fact (including, but not limited to statements that contain words such as “will,” “believes,” “plans,” “anticipates,” “expects,” “estimates”) should also be considered to be forward-looking statements. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of potential products, uncertainty in the results of clinical trials or regulatory approvals, need and ability to obtain future capital, and maintenance of intellectual property rights. Actual results may differ materially from the results anticipated in these forward-looking statements and as such should be evaluated together with the many uncertainties that affect the businesses of Asterias, particularly those mentioned in the cautionary statements found in Asterias’ filings with the Securities and Exchange Commission. Asterias disclaims any intent or obligation to update these forward-looking statements.

Contacts:

Investor Relations
(510) 456-3892
InvestorRelations@asteriasbio.com

or

EVC Group, Inc.
Michael Polyviou/Greg Gin
(646) 445-4800
mpolyviou@evcgroup.com

ASTERIAS BIOTHERAPUTICS, INC.

CONDENSED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE DATA)

	Three Months Ended		Nine months ended	
	September 30,		September 30,	
	2016	2015	2016	2015
REVENUE				
Royalties from product sales	\$ 218	\$ 353	\$ 337	\$ 528
Sale of cell lines	-	-	-	40
Grant income	1,858	1,070	4,865	2,406
Total revenue	2,076	1,423	5,202	2,974
Cost of sales	(59)	(176)	(118)	(265)
Total gross profit	2,017	1,247	5,084	2,709
EXPENSES				
Research and development	(5,232)	(4,629)	(17,594)	(11,918)
General and administrative	(4,210)	(1,554)	(13,081)	(5,071)
Total operating expenses	(9,442)	(6,183)	(30,675)	(16,989)
Loss from operations	(7,425)	(4,936)	(25,591)	(14,280)
OTHER INCOME/(EXPENSE)				
Change in fair value on warranty liability	(3,995)	-	(2,368)	-
Interest expense, net	(128)	(126)	(413)	(197)
Other expense, net	(2)	(6)	(27)	(7)
Total other expenses	(4,125)	(132)	(2,808)	(204)
LOSS BEFORE INCOME TAX BENEFIT	(11,550)	(5,068)	(28,399)	(14,484)
Deferred income tax benefit	902	1,561	2,255	4,386
NET LOSS	\$ (10,648)	\$ (3,507)	\$ (26,144)	\$ (10,098)
Basic and diluted net loss per common share	\$ (0.24)	\$ (0.09)	\$ (0.63)	\$ (0.29)
Weighted average common shares outstanding: basic and diluted	45,193	37,602	41,588	34,643

ASTERIAS BIOTHERAPUTICS, INC.
CONDENSED BALANCE SHEETS
(IN THOUSANDS, EXCEPT PAR VALUE AMOUNTS)

	<u>September 30,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 17,926	\$ 11,183
Available-for-sale securities, at fair value	15,999	17,006
Landlord receivable	-	567
Prepaid expenses and other current assets	1,989	1,033
Total current assets	<u>35,914</u>	<u>29,789</u>
NONCURRENT ASSETS		
Intangible assets, net	18,802	20,816
Property, plant and equipment, net	5,212	5,756
Investment in affiliates	-	416
Deferred tax asset	9,956	9,744
Other assets	419	457
TOTAL ASSETS	<u>\$ 70,303</u>	<u>\$ 66,978</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Amount due to BioTime, Inc.	\$ 463	\$ 530
Accounts payable	640	747
Accrued liabilities and other current liabilities	981	1,183
Capital lease liability	7	7
Deferred grant income	1,392	2,513
Deferred tax liabilities, current portion	5,393	5,274
Total current liabilities	<u>8,876</u>	<u>10,254</u>
LONG-TERM LIABILITIES		
Capital lease liability	21	26
Warrant liability	8,376	-
Deferred tax liabilities, net of current portion	5,963	7,020
Deferred rent liability	251	179
Lease liability	4,090	4,400
TOTAL LIABILITIES	<u>27,577</u>	<u>21,879</u>
STOCKHOLDERS' EQUITY		
Preferred Stock, \$0.0001 par value, authorized 5,000 shares; none issued and outstanding	-	-
Common Stock, \$0.0001 par value, authorized 75,000 Series A Common Stock and 75,000 Series B Common Stock; 45,857 and 38,228 shares Series A Common Stock issued and outstanding at September 30, 2016 and December 31, 2015, respectively; no Series B Common Stock issued and outstanding at September 30, 2016 and December 31, 2015	5	4
Additional paid-in capital	117,452	92,900
Accumulated comprehensive gain (loss) on available-for-sale investments	(348)	434
Accumulated deficit	(74,383)	(48,239)
Total stockholders' equity	<u>42,726</u>	<u>45,099</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 70,303</u>	<u>\$ 66,978</u>

Company Name: Asterias Biotherapeutics Inc (ASTB)
Event: Q3 2016 Earnings Conference Call
Date: November 14, 2016

Operator: Good day, and welcome to the Asterias Biotherapeutics Q3 Conference Call. Today's conference is being recorded. At this time, I would like to turn the conference over to Doug Sherk. Please go ahead.

<<Douglas Sherk, Investors Relations, EVC Group>>

Thank you, Kyle, and good afternoon, everyone. Thank you for joining us today, November 14, 2016, for the Asterias Biotherapeutics conference call and webcast to review the company's third quarter results and recent accelerated clinical progress.

This afternoon, after the market closed, Asterias issued its results release, which is posted on the company's website at www.asteriasbiotherapeutics.com. Today's call is also being broadcast live via webcast. To access the webcast, go to the Asterias's website, click the Investors link and then click on Events and Presentations. There will be a taped replay of this call, which will be available approximately two hours after the call's conclusion and will remain available for seven days. The operator will provide the replay instructions at the end of today's call.

Before we get started, we would like to remind you that during the course of this conference call, the company will make projections and forward-looking statements regarding future events. We encourage you to review the company's past and future filings with the SEC, including without limitation in the Company's Forms 10-K and 10-Q which identify the specific factors that may cause actual results or events to differ materially from those described in these forward-looking statements.

These factors may include without limitation, risks inherent in the development and/or commercialization of potential products, uncertainty in the results of clinical trials or regulatory approvals, need and ability to obtain future capital and maintenance of intellectual property rights. One final note, during the question-and-answer session this afternoon, please limit yourself to two questions, and then re-queue if you have additional questions.

And now with that out of the way, I'd like to turn the call over to Steve Cartt, President and Chief Executive Officer of Asterias.

<<Stephen Lahue Cartt, President, Chief Executive Officer & Director>>

Thanks, Doug, and thanks everyone for joining us today. With me today are several other members of our management team including Katy Spink, our Chief Operating Officer; Ed Wirth, our Chief Medical Officer; Ryan Chavez, our EVP of Finance and General Council; and Jane Lebkowski, our Chief Scientific Officer.

We are also very fortunate to have two guests with us today including Dr. Shekar Kurpad, a clinical investigator for our ongoing OPC1 SCiSTAR study and spinal cord injury patients. Total discussions experienced today with OPC1 and its institution and will be joined by one of his patients, Lucas, who several months ago was administered 10 million cells of OPC1 as part of the ongoing SCiSTAR study. Dr. Kurpad will talk about his experience a little later on the call. Both he and Lucas will be available to answer questions during the Q&A session.

The agenda for today's call will include a brief overview of our third quarter as well as recent progress made in our SCiSTAR clinical study also provide a brief update on our cancer immunotherapy program: VAC1 and VAC2. Ed will follow me with additional details about our OPC1 program and then turn the call over to Dr. Kurpad. Ryan will then take you through a summary of our financial results after which we'll open up the call for questions.

Since we last spoke with you in September, we continue to make good progress in the SCiSTAR study evaluating OPC1, our pluripotent stem cell derived treatment for patients with spinal cord injuries because there are about 17,000 people who suffer from spinal cord injuries every year in the U.S. alone. These devastating injuries result in very high healthcare costs, which can sometimes reach \$5 million over the course of a person's lifetime.

Today, we're going to provide an important and quite exciting update on the study. We've recently seen a significant acceleration in enrollment and dosing of patients in the SCiSTAR study. And as a result and that goes two AIS-B patients with ten million cells and two AIS-A patients with 20 million cells. So enrollment of both of these recently initiated cohorts is well underway.

We announced just last week that the first AIS-A patient with complete cervical spinal cord injury was successfully treated with a maximum dose of 20 million OPC1 cells. And since then as we noted in today's press release, we've already dosed our second AIS-A patient with 20 million cells. In addition, we successfully dosed the first patient with incomplete AIS-B cervical spinal cord injury with 10 million OPC1 cells in late September and last week noted that we have also dosed our second AIS-B patient.

So in summary, while our very first three patients in the study took several months to enroll, our most recent three patients were enrolled and dosed in the span of about a week. We're excited about the accelerated patient enrollment since this continues that carries the potential for completing the study earlier than expected and getting on with the next phase of development.

As a result over the next few months, we'll be assessing our enrollment rate trends in order to re-evaluate our study timelines between now and our January release date providing a study timeline update at that time. In a few minutes, Ed will talk about several factors that are working together to drive the clear uptick in enrollment activity, but at this point I'd like to remind everyone about the positive early efficacy data from the 10 million cell AIS-A cohort that we announced in September.

Recall that the results showed meaningful improvement in motor function, particularly in the use of patients' hands, fingers and arms. This type of improvement is critically important for a patient's quality of life and ability to function independently. They can often allow a patient to be better able to address him or herself, eat and drink without assistance. They operate a wheelchair, hold a job, drive a car equipped with hand controls, and generally engage in activities of daily living.

There has been a lot of excitement about this initial look at efficacy, but as we have noted in many investors meetings over the last several weeks, an important step is going to be why these improvements are sustained over a longer period of time. So the six month data readout in January is going to be an important indicator whether these gains are maintained.

We believe results will be sustained based on our preclinical research that having data in actual human patients that confirm that these early improvements are sustained; will be a significant clinical achievement for the OPC1 program as well as for our Asterias pluripotent stem cell technology in general.

Concurrent with the efforts and progress around our lead OPC1 program, we're continuing to advance our clinical stage development programs in cancer immunotherapy, which include VAC1, a patient-specific cancer immunotherapy, and VAC2, a non-patient specific approach to cancer immunotherapy. As a reminder, both of these investigational therapies target the telomerase protein that is present in 95% of all cancers.

So we believe there is the potential for broad utility across multiple types of cancer with VAC1 and VAC2. Regarding VAC2, we're working with our development partner, Cancer Research UK, to initiate the first Phase 1/2a clinical trial in non-small cell lung cancer. The clinical trial will examine the safety, immunogenicity, and activity of VAC2 and may position this new cancer immunotherapy to be tested not only in non-small cell lung cancer, but also in other cancers as well.

The clinical trial protocol is closed to being finalized and we anticipate a January filing for clearance from the UK regulatory authorities to be able to start the study. We expect to get regulatory clearance in the first quarter of 2017 in order to be able to begin the first VAC2 clinical study and expect our first patient enrollment in the second quarter of 2017.

Next, I'll turn briefly to VAC1, which we are developing for maintenance of remission in patients with acute myeloid leukemia. Process development is ongoing for VAC1, focused on creating a modernized, faster, more cost-effective manufacturing process that can efficiently supply clinical trial material and eventually, if all goes well, commercial product. We anticipate completing these process development activities sometime next summer.

And with that, let me turn the call over to Ed Wirth, our Chief Medical Officer, who will provide more details on the recent progress of our OPC1 program. Ed?

<<Edward D. Wirth, Chief Medical Officer>>

Thanks, Steve. Good afternoon, everybody. We have been focused on continuing to enroll patients for the SCiSTAR study and we are pleased with the recent acceleration that we had seen. This process is going very well due to the continued favorable safety profile of the AST-OPC1 injection procedure, which has enabled us to obtain FDA clearance for simultaneous enrollment of AIS-A and AIS-B patients, as well as a significant reduction of the required staggering between patients. In addition, we opened a three additional clinical sites earlier this year which doubled the number of open sites to six.

Another key driver of the enrollment acceleration has been the large increase in a number of inquiries from friends and relatives of newly injured patients, which may be a result of the significant media coverage of the interim efficacy data that we presented in September. As Steve mentioned, we have now treated two AIS-A patients with highest dose of 20 million cells of OPC1 in SCiSTAR clinical trial, a total of five to eight patients are expected to be enrolled in this cohort. Based on extensive pre-clinical research, this is in the dosing range where we would expect to see optimal clinical improvement in these patients.

Dose escalation to 20 million cells followed the Data Monitoring Committee's independent safety review of the data from the initial three patient cohort receiving 2 million cells and the five AIS-A patient cohort dosed with 10 million cells and was based on OPC1's continued favorable safety profile observed in the SCiSTAR study. We've been very encouraged by the early clinical efficacy and safety data for OPC1 and we now look forward to evaluating AIS-A 20 million cell dosed in patients. We expect to have data evaluating efficacy results from this maximum dose cohort later in 2017. As we previously stated, we expect to report top line six month efficacy and safety results from the five AIS-A patients treated in the 10 million cell cohort in January of 2017.

We are also focused on expanding enrollment of the SCiSTAR study to improve incomplete AIS-B cervical spinal cord injury patients. In September, we successfully dosed the first AIS-B patient with 10 million cells of OPC1 and the SCiSTAR clinical trial at Shepherd Center in Atlanta. Enrollment continued in this cohort and a second AIS-B patient has been dosed. A total of five to eight AIS-B patients are expected to be enrolled and dosed with 10 million cells in the study.

Let me provide a brief background on the distinction between AIS-A and AIS-B spinal cord injuries. AIS-A patients are characterized by cervical spinal cord injuries resulting in complete loss of motor and sensory function below the cervical injury sites. While AIS-B patients have similar cervical injuries and complete motor loss but retain some sensory function due to having more spare tissue in their spinal cords. Due to the greater amount of spared spinal tissue at the injury site compared to AIS-A patients. We believe AIS-B patients may have a greater chance of meaningful functional improvement after being treated with OPC1 cells.

Given the progress we've seen and evaluations of OPC1 and people with AIS-A injuries, particularly improvements in hand, finger and arm function; we're excited to continue the evaluation of this promising new treatment in AIS-B patients. This important trial expansion extends the range of spinal cord injury patients being evaluated, helps increase the number of patients evaluated for efficacy and safety and will help us design further clinical trials at OPC1 that could support a potential accelerated regulatory pathway should we observe sufficiently positive efficacy signals and continued safety in the study. In addition, during third quarter we reported promising interim efficacy data for OPC1 from five AIS-A patients that had been dosed with 10 million cells in the SCiSTAR study.

The results discussed in September from this cohort while still early demonstrate meaningful improvement in upper extremity motor function, particularly in the use of the patient's hands, fingers and arms, which is critically important for a patient's quality of life and ability to function independently. The data were presented at 55th Annual Scientific Meeting of the International Spinal Cord Society in Vienna, Austria. Some of the highlights from this presentation included; first, all patients have exhibited improved upper extremity motor scores relative to baseline and have improved at least one motor level and the efficacy target of two or five patients in the cohort achieving two motor levels of improvement on at least one side of their body was achieved. So these data reached at least 6 to 12 month efficacy endpoint within three months.

Second, as Day 90 a follow-up, four out of four patients had improved one motor level on at least one side, two out of four patients had improved two motor levels on at least one side, and one patient had improved two motor levels on both sides.

Third, the average upper extremity motor square improvement at Day 90 for the 4 patients that had reached this follow-up was 9.5 points compared to 5.0 points at Day 90 for patients dosed with 2 million cells which may also begin to support a dose response for OPC1.

Four, the results from the 10 million cell cohort show no serious adverse events related to OPC1, the injection procedure or immunosuppression with low dose tacrolimus to-date. In addition, data from this study indicate that OPC1 can be safely administered to patients in the sub-acute period after severe cervical spinal cord injury.

Patients are being monitored for improvement in motor function by using ISNCSCI neurological classification scale which is widely used to quantify muscle function in patients with spinal cord injuries. As suggested by existing research in patients with complete cervical spinal cord injuries, a two motor level improvement is correlated with a significant increase in functional ability, as well as the ability for patients to care for themselves since so many activities of daily living are dependent on arm and hand function.

We hope that we are able to see the early, but very encouraging efficacy trends continue as the study progresses. We're looking forward to six months results from the 10 million cell efficacy cohort in January 2017 which will focus on improvement in physical functioning of the upper extremities i.e. that is hands, fingers, and arms of each treated patient.

Now I'd like to turn the call over to Dr. Shekar N. Kurpad. Dr. Kurpad is Interim Chair and Professor of Neurosurgery, Director, Spinal Cord Injury Center and Director, Spine Surgery Fellowship at the Medical College of Wisconsin, and one of the investigators for the OPC1 SCiSTAR study. Dr. Kurpad specializes in the treatment of both, spinal and cranial disorders; his clinical expertise lies in surgery for spinal trauma, tumors of the spine and spinal cord, degenerative disease of the spine, spinal deformities, cell-based tumors, general neurosurgery, and minimally invasive methods for the treatment of spinal disorders.

Dr. Krupad also has extensive research experience in spinal cord injury. Dr. Krupad will be providing perspective on his experience to-date with OPC1 and what he has seen so far in this study at Medical College of Wisconsin. This is a particularly special opportunity on the call today and that Dr. Krupad has been joined on the call by one of his patients, Lucas, who received a dose of 10 million cells of OPC1 a few months ago.

Please go ahead, Dr. Kurpad.

<<Shekar N. Kurpad, Director, Spinal Cord Injury Center & Director, Spine Surgery Fellowship at Medical College of Wisconsin>>

Thank you very much Dr. Wirth and Steve Cartt. I appreciate the opportunity to be part of this call, and good afternoon to everybody else on the call. Dr. Wirth summarized my qualifications. I just want to make my comments brief and really give a surgeon and a physician's perspective on the efficacy that I have so far observed treating patients with OPC1 cells and thus SCiSTAR study.

I have about 20 years of experience in the clinical care and in the research of spinal cord injury, both from a molecular standpoint, as well as an imaging standpoint and I've treated a number of patients with spinal cord injury with our center averaging approximately 30 to 40 new spinal cord injury patients every year.

I have been part of seven different clinical trials as a principal investigator at the Medical College of Wisconsin which has a very long-standing Spinal Cord Injury Center, the only one of its kind in the State of Wisconsin. In the seven trials, I believe that the SCiSTAR study is the only one that I'm aware of, that I've seen this type of clinical improvement at Day 90 after the transplantation of cells has been performed. One of my patients, the second one, the second patient that I performed the transplantation on, Lucas Linder, is going to follow me on this call with some of his comments.

Both patients at our institution were dosed with 10 million cells and both experienced significant improvement. Lucas, who is my second patient, is now approximately five months post-op, we had the chance to meet at his 90-day follow-up, as well as today, earlier in the day where there has been a remarkable increase in his motor strength based on formal neurological examinations.

What really – you've already heard from Ed Wirth about improvement in the ASIA Motor-Score in terms of the number of points in the dose response curve but from a practical standpoint what is really impressive to me is that there's clearly evidence of return of at least one and perhaps two levels of function in both cases that I have treated who are ASIA A at the time of injury. Because of the additional function that they have obtained, Lucas, for example, is now able to significantly increase the use of his fingers and hands allowing him to type at significantly high rates and able to actually type 30 to 35 words a minute, which is quite incredible in a person that had no use of his hands and fingers whatsoever prior to the transplantation.

Because of the consistency of improvement in function across the patient population, I'm particularly impressed and think even as a dubious scientist that this is much more of an improvement over what might be observed without treatment. So overall, I'm extremely impressed with the amount of improvement that both of my patients have experienced.

I also want to say just a couple of words about the surgical procedure itself. I believe having done a number several thousand spinal procedures, I believe that delivering these cells from a technical standpoint is relatively straightforward, especially in the context of the complexity of neurosurgical operations and really is quite accurate in terms of getting the apparatus that we have to deliver the cell to the desired spot within the injured spinal cord is quite accurate, and is pretty facile, and quite generalizable to a larger neurosurgical practitioner when this becomes more common place in its use.

I'll leave it at that for Lucas to join in the call and then be available for questions.

<<Stephen Lahue Cartt, President, Chief Executive Officer & Director>>

Go ahead, Lucas.

<<Unidentified Company Representative>>

All right, thank you. Initially before the treatment, I had very, very little control of my wrist and almost no control at my fingers. I couldn't raise my arms up to about the point where my elbow would have been level with my shoulders. And that was right before I got the treatment. And then after I received the OPC1, it was probably about a week and-a-half before I started seeing results. And once the results started coming it was slow at first and picked up and I could really notice everything around probably about a month afterwards.

And at that point I could move each one of my fingers, my both hands independently, which I couldn't do it all before. So that gave me the ability to be able to text, to be able to type and it's been really remarkable, the transition to being able to do something again, and be productive and take care of myself, which is really the big thing. I wasn't able to feed myself or really bring up a cup of water to take a drink before getting the treatment. And now, not only can I drink the water I can go right up to the sink and operate the faucet and everything.

I think looking to the future, I think the biggest thing that I'm going to have gained from the treatment is being able to find employment and find a career path that will allow me to be successful, and support myself and live a relatively normal life that wouldn't at all be possible had I not – had the movement and dexterity that I do now, I think it's really huge where I've gotten in the last couple of months here. Yes, that's about it.

<<Stephen Lahue Cartt, President, Chief Executive Officer & Director>>

That's great. Well, I'd like to thank Dr. Kurpad for sure, but I'd also like to thank Lucas in particular. Lucas is a young guy, he's been through a lot and he's been involved in the study and he really wanted to share his experience on the call here with everybody, investors, and analysts and alike. So Lucas, we really appreciate you being on the call. And both of them will be available on the Q&A a bit later.

So now I'd like to turn the call over to Ryan, who will discuss more mundane matters with financial results. Ryan?

<<Ryan Chavez, Executive Vice President of Finance & General Counsel>>

Yes, hard to follow that. So thanks Steve and good afternoon everyone. So I'm going to focus today on our cash position and usage. As of September 30, 2016, cash, cash equivalents and available-for-sale securities totaled \$33.9 million. Net cash used from operations for the nine months ended September 30, 2016 was \$15.1 million and net cash used for operations for the quarter was approximately \$5.1 million.

After the quarter closed, as Steve and Ed mentioned, we recently dosed the first AIS-A patient with 20 million cells, which triggered an additional \$2.5 million grant payments from CIRM, which we expect to receive on the fourth quarter this year. This grant payment is part of the existing \$14.3 million non-dilutive grant that we've previously received from CIRM. And based on estimated burn rates, we believe the Company's current cash, cash equivalents and marketable securities as of the end of the quarter are sufficient to continue to fund operations through the third quarter of 2017.

Now I'll turn the call back to Steve for concluding remarks before we go to Q&A.

<<Stephen L. Cartt, President and Chief Executive Officer>>

Thanks, Ryan. In summary, we continue to advance our three clinical stage cell therapy programs. Our near-term top priority of course is to rapidly enroll the OPC1 SCiStar study. We're quite excited with the success of our efforts and accelerating the patient enrollment and are now seeing the initial results of these efforts. We look forward to updating you on our further progress including the critically important six-month efficacy and safety data from the 10 million cell AIS-A cohort in January and we expect to report on additional important milestone throughout 2017.

Before opening the call up for questions, I'd like to address a question that recently has been coming up fairly often in discussions with our investors. That question is as follows, there was another company with an earlier program using stem cells and spinal cord injury patients that recently failed and was shut down. Is the OPC1 program any different? Well, the answer is that the OPC1 program is dramatically different. Here is why. First, the earlier program conducted their study in patients with long-existing spinal cord injuries.

All the Asterias pre-clinical work indicated that the development of scar tissue at the spinal cord injury site keeps from injecting cells from dispersing properly within the injury site, rendering them ineffective. So we were always very skeptical that the earlier program would be successful. That is why our study enrolls only patients with very recent injuries before scar tissue can develop.

Second, the earlier failed program utilized fetal tissue in its research. This is quite problematic for a number of reasons that I won't get into on this call, but the main one from a therapeutic perspective is that fetal tissue is highly variable in terms of the type and quality of cells it provides. Asterias has never utilized fetal tissue for any purpose, instead we use only a highly consistent, highly purified line of pluripotent stem cells, first created in the late 1990s. The cells from the cell line can be massively replicated to the extent that it would be able to supply the entire life cycle for OPC1 including all future commercial needs. It means two critically important ways, our OPC1 program is very, very different and we are quite encouraged by what we are seeing so far in our current clinical study.

So with that, operator, Mickie, you may now open up the call to questions.

Q&A

Operator: Thank you. [Operator Instructions] And we'll take our first question from Reni Benjamin with Raymond James.

<Q – Bin Lu>: Hi, guys. This is Bin Lu on behalf of Reni. Thanks for taking my questions, again congrats on the progress made for the quarter. It's very impressive. I have two questions. So maybe first one is for Dr. Kurpad. I think you mentioned that the level of motor, level improvement is very impressive. And so can you just provide additional color regarding this improvement of 40%? Do you think that this rate, if it is maintained in larger study, do you think it's going to be sufficient to support approval as well as clinical adoption after approval?

<A – Shekar N. Kurpad>: Thank you for your question. I'm very impressed with the amount of improvement and specifically, I want to go a little bit more detail into the answer. If you see a patient with a mid-cervical or C5 cervical spinal cord injury and you're able to confer upon that patient just two to three levels of improvement between C5 to C8 versus C6 to T1, the lateral which we have seen in Lucas' case, it's difference between being able to use your hands versus not. Essentially, in a patient with a C5-C6 injury, you've taken someone that can barely move in a very crude fashion both arms together to where you render the patient able to transfer themselves from a bed to a chair, or from one chair to another, or from a chair to the driver's seat of a car and then use their hands in a way that they can make themselves and they can be independent. So you've conferred the ability to transfer, you've conferred the ability for patients especially the young patients that are the most common patients that have these types of problems, to be able to live essentially a normal life in terms of being able to text, in terms of being able to type.

One of the things that I did not mention today was when I saw Lucas, I had him do various activities like he'll lift his laptop, and then open his laptop, and then start to type messages on his laptop, pick up his phone from a surface, and then text messages on his phone. He also brought back to show me how he could take a two-by-four and drill screws in, remove screws from using wrench. I was told by the grandparents that he assembled a wall-mounted television – did everything on it except mount it to the wall. So these are just examples of various 'normal day-to-day activities' that a person can do who has the use of their hands. So to summarize the answer to your question, is I think a substantive quality of life improvement is obtainable, just with a two-level improvement which we are seeing in multiple patients so far in both cohorts and I think if this continues, I think this is almost certainly going to become a treatment modality – a viable treatment modality.

<Q – Bin Lu>: Great. Thanks. That's very helpful. And then I have one more question for Steve. I think on the call you mentioned that the enrollment has been accelerated in the past week. We got a three patient enrolled. I think my understanding is usually the instance of spinal cord injury decreases after summer. So given this accelerating enrollment in the past week, can you provide some color regarding why this occurred? Have you done something to drive the enrollment? And then if that's the case, are we going to see this level of enrollment going forward for all the cohort and then you might revise your timeline for the studies. Thanks.

<A – Shekar N. Kurpad>: Yes, it's a good question. There are a lot of causes at these types of injuries and a lot of people think of more summer activities – diving in pools, in lakes, and things like that. But a fair number of them like in Lucas' case were auto accidents. Those obviously can happen in the fall, in the winter, as well as summer. But Ed Wirth who's our Chief Medical Officer has a lot more experience than I do on this topic, so I'll let Ed comment as well as to what's contributing to the faster recent enrollment rates.

<A – Edward D. Wirth>: Yes. Thanks, Steve. Yes, we think it's a combination of factors that are all coming together to accelerate this enrollment, even as we get into the latter months of the year. The key factors we're seeing are that again, there have been quite a bit of a tension about the study for many corners through the national media and so forth and additional clinical sites. That seems to be dovetailing with the ongoing outreach that we've been doing to healthcare providers throughout the country who treats spinal injury patients and also continuing to talk with potential additional sites. And as we've mentioned previously, we do intend to open several additional clinical sites for the study in the coming months and some of that outreach effort has already resulted in referral of the patients for the trial.

So it's a combination of factors and then of course as I mentioned earlier on the call today, the fact that we're now able to enroll both AIS-A patients, AIS-B patients simultaneously has also been a major contributing factor to the acceleration. So really it's all of these different factors coming together now that really has resulted in the enrollment phase picking up.

<Q – Bin Lu>: Great. Thanks for the color. Good luck going forward.

<A – Edward D. Wirth>: Thank you.

Operator: We'll take our next question from Keay Nakae with Chardan.

<Q – Keay Nakae>: Yes, thank you. Pretty compelling stuff here. I want to wish Lucas the best of luck going forward. First of all, in terms of the number of sites currently open, can you tell us how many have actually enrolled the patient and then how many additional sites would you expect to bring on board in the coming months?

<A – Edward D. Wirth>: Yes. So, we currently have six sites open for enrollment, they're all listed on our study website and clinical trials that have gone, so the names and so forth and contact info, all there. Of those six, five have already dosed subjects. The sixth site hasn't dosed subject, although, it did have an eligible subject that have gotten referred to one of our other clinical sites in the patient's home town, so all six have been very active in participating in the study.

Going forward again, we anticipate opening several additional sites in the coming months, and that will be opened up around the country and we expected that will provide further acceleration to the overall enrollment timeline.

<Q – Keay Nakae>: Okay. And for Dr. Kurpad, in your experience in terms of spontaneous recoveries, if a patient hasn't shown this level of improvement whether it's one or two levels by 90 days or six months, what's so likely here that will exhibit a spontaneous recovery after that period of time in your experience?

<A – Shekar N. Kurpad>: I'd say the short answer to that is very low. I think in terms of actual numbers, if you looked at a cohort of patients that had an AIS-A injury and followed them with only rehab for a year, up to about 10% of patients might change to a slightly better grade, not necessarily two levels, but slightly a better grade, some subset of that. But even in those patients that get better, the predominant number of those patients do show – show signs of doing so within the first three months. So at this point, I think this is – as an investigator, I'm pretty convinced that this is likely due to the intervention of either of OPC1 transplantation.

<Q – Keay Nakae>: Okay. And then for Dr. Kurpad or Dr. Wirth, the common question I get is how do we distinguish your results to-date from the spontaneous recovery rates? The off-site at numbers are maybe 21% at three months and maybe up to 25% at six months. How good are those numbers to use as a comparison? Are those well-established? Just give us some thoughts on those.

<A – Edward D. Wirth>: Maybe I can comment on that, yes. Where those historical numbers come from is a very thorough evaluation of all of the major pharmacology databases in the U.S. and then Europe. That was then led by Dr. John Steves and those data were published in a pay-per-view site. I'm happy to provide that to you. What we're going to be looking at going forward is how is this percentage of two motor level recovery and overall arm and hand function recovery. How is it looking at six months and also 12 months out next year?

And in addition, now though we began those things, it should be in AIS-A patients with 20 million cells and the AIS-B patients with 10 million cells will have multiple data readouts next year, that should give us a much better idea of what the overall signal is looking like. So I think by this time next year, we'll have multiple additional readouts that will give us a pretty good sense of how strong the clinical signal is.

<Q – Keay Nakae>: Okay. And then just lead to my final question and that is with respect to the AIS-Bs, given that they are less severe at the time of injury, what are the spontaneous recovery rates for those patients? What do those look like at three and six months?

<A – Edward D. Wirth>: The AIS-B patients generally have a similar rate of motor recovery to the AIS-A patients. If they're similar to an AIS-A patient at one month out after injury, which our patients are in that baseline, they have the same general prognosis for motor recovery, the AIS-As, and perhaps Dr. Kurpad can comment on that as well. But the published data that we've seen again from Dr. Steve's and others is for AIS-B at one month out who has similar motor function, AIS-A, from that point going forward they are pretty similar. Dr. Kurpad, do you mind to comment as well?

<A – Shekar N. Kurpad>: So, in response to the second question, I agree substantively with Dr. Wirth. And with response to your first question, the numbers of 21% and 25%, the current cohort of five patients at 10 million cells clearly is superior to the 21% by a large margin. It's a small number of patients, but the results are significantly sphere in terms of recovery at the 90-day period.

In addition, the other thing that encourages me is that there seems to be as Dr. Wirth pointed out earlier at his general comments, that those response based on comparing the 2 million cell cohort or 10 million cell cohort, I'd be very keen on looking at what happens with the 20 million cell cohort, but I think so far, the results clearly indicate number one, that this is better than chance or natural history, and number two, that there seems to be a clear suggestion of a dose response curve which also suggest that it's treatment effect as opposed to natural history.

<Q – Keay Nakae>: Okay, very good. Thanks for that.

<A – Edward D. Wirth>: Thanks, Keay.

Operator: We'll take our next question from Christopher James with FBR & Co.

<Q – Christopher S. James>: Hi, good afternoon. Thanks for taking the question, maybe a few for Dr. Kurpad. What level of – you mentioned C5 a number of times. What level of cervical spinal cord injury do you expect the greatest improvement and then secondly, how do you expect to incorporate the transplantation of cells with other interventions including instrumentation, fusions, as well as the use of steroids? Then I have a follow-up.

<A – Shekar N. Kurpad>: I'll answer those questions in four parts. We'll take the instrumentation first. These patients that are dosed are typically already instrumented because the window for treatment with the OPC1 begins at about three weeks after the original injury by which time we've already seen patients who have been treated at potentially outside centers, or our own center in our case and they present with pre-placed instrumentation.

So typically sometimes, the procedure as have been in the case of Lucas involves revision of the instrumentation, which in his case was quite straightforward and I don't see that it will be any different in any other patient because it's like a redo operation and we do – spine surgeons generally do a lot of redo operations. So I don't see that as an additional technical barrier. With respect to – I'm sorry, can you refresh my memory about the other two questions?

<Q – Christopher S. James>: So the other questions were regarding use of steroids and then what level of injury do you expect the greatest impact?

<A – Shekar N. Kurpad>: Yes, thank you. So with regard to the level of injury and the greatest impact, I think in patients with C5 or C6 injuries who do not have tangible triceps function and tangible function for the use of the hands and fingers, those are probably the patients that are in my opinion the highest likelihood of significant functional improvement. These are patients that are probably not ventilator-dependent given that their injuries are at C5 and C6, but are significantly dependent on additional care because they cannot transfer themselves, nor can they use their hands effectively. So I think those patients can go from being completely dependent, to being essentially employable and relatively independent, save for the care of their bladder, and bowel, and lower extremities and so on.

So that segment of the spinal cord injury population I think is probably going to see the biggest functional difference. It remains to be seen what would happen in patients with a higher level of injury i.e. those that are ventilator-dependent, could they achieve ventilator independence for example or even more, gain even more function like a C6 or C7 function that would make them independent like the other population of C5 and C6 that we just talked about. So that would be my guess as to which patient population that would be most benefited from the treatment.

<Q – Christopher S. James>: Got it. So is it fair to say that C3, C4, C5, I guess the goals will be different? Just more diaphragmatic control and getting patients off of ventilator, or are we thinking about this correctly?

<A – Shekar N. Kurpad>: Yes. I think if you assume two to three level improvement, I think getting a vent-dependent patient off the ventilator would be a very reasonable and modest goal if you're looking at a two-level improvement and for a C5, C6 quadriplegic to get them from a status of functional dependence to relatively complete functional independence.

<Q – Christopher S. James>: Okay and then one final follow-up. You mentioned you've done a lot of work with imaging. I think I've asked this in the past. Are there any opportunities – do you see any opportunities to use any imaging in these patients? Does it correlate with the motor function that you're observing?

<A – Shekar N. Kurpad>: Absolutely. I think imaging technology is evolving alongside treatment modalities, such as the one we are discussing at the moment and I think there is still a lot of uncertainty, but I think the pace at which the imaging technology is progressing, in terms of how to correlate specific MRI-based imaging findings to function, it's going pretty fast and I think we're not far away from having a biomarker, which will help us not only assess prognosis better, based on the profile that we visualize of the spinal cord, but will also might help us guide treatment delivery. In other words, where do we put specific spot do we inject the cells, or set a spot that we inject the cells? That imaging might also in my mind be a guide towards more accurate delivery of the cells in the future.

You also have asked the question about steroids. That's a whole another topic. As you know, steroids used to be in common place used. Now it is really not the WNS and the CNS guidelines – the most recent set of guidelines actually do not recommend the use of high dose steroids after acute spinal cord injury and we're one center that we don't administer steroids anymore.

Obviously, the purpose of steroids was to reduce early inflammation, but there has not been found to over a number of years, over a number of studies, which we can go into if there's time, there has not been observed a clear benefit that was originally thought to exist. So we've actually delegated the use of steroids to simply being an option as opposed to a requirement.

<Q – Christopher S. James>: Got it. Thank you.

Operator: We'll take our next question from Bruce Jackson with Lake Street Capital Markets.

<Q – Bruce D. Jackson>: Hi. Congratulations on all of the progress. Just a couple of questions. With the presentation or the release of the 10 million cell cohort data, is that going to coincide with a medical meeting? Or is that just something where you'll put out a press release?

<A – Stephen L. Cartt>: Yes. Bruce, I don't think there's an appropriate medical meeting in that timeframe. There are similar, but later in the year, but we'll probably just put out as a news release and likely a call to discuss the results and what they might need. But Ed, do you want to add anything to that?

<A – Edward D. Wirth>: That seems correct. So yes, then we haven't found the meeting in that timeframe that we think to be appropriate, so but there are other meetings that will be coming up in the following months that we'll be making presentations in addition to probably a press release and a call in the January timeframe.

<Q – Bruce D. Jackson>: Okay, great. Then my next question is about the efficacy levels. So we saw 40% in the early data. If the efficacy level goes up, is it possible that it could reach 60%? Would 60% be a threshold at which you could seek accelerated registration and would you be able to do that off of this particular cohort?

<A – Stephen L. Cartt>: Yes. It's a very good question. It's kind of too preliminary to speculate on that. It's something that we are definitely going to be evaluating in the coming weeks. But I actually have Jane Lebkowski here who's our Chief Scientific Officer and our main regulatory liaison with FDA. And Jane, do you want to add anything to that?

<A – Jane S. Lebkowski>: Yes. I think we need to see what the data is going to look like, not only the 10 million dose cohort, but it's the 20 million dose cohort and under those circumstances that data will be very important to lead us to the design of future clinical trials. If the data looks exceptionally good, then we would be able to have the potential accelerated registration process. So again, it's really important to look at the degree of efficacy, the duration of that efficacy and then help us use that design in future trials.

<Q – Bruce D. Jackson>: Okay, great. And then the acceleration in the recruitment of the 20 million cell cohort is very encouraging. You said that we might see data later in 2017. Could you be just a little bit more specific on first half, second half or even in a particular quarter?

<A – Stephen L. Cartt>: I think there are done at least half of the year. So we would anticipate having at least the first five AIS-A patients dosed with 20 million cells by the end of the first half of next year with a six-month readout, then in the second half of the year. Hard to narrow down the precise quarters because sometimes you get several patients at once and then sometimes there's a bit of a gap. But certainly, we would anticipate completing enrollment of those AIS-A in the first half of the year with the six-month readout in the second half.

<Q – Bruce D. Jackson>: Okay, great. And then just real fast question for Dr. Kurpad, sometimes with trials like this, it can be really challenging to recruit patients who have got fairly specific inclusion criteria, a lot of paperwork. Have you found that the company has done everything to help you out and has it been any kind of an impediment to finding our recruiting potential patients for the trial?

<A – Shekar N. Kurpad>: That's a very good question. And I cannot say enough about how much support we've had from the company. And this is not simply something that ends with helping recruitment, but this includes the logistics of once we do recruit somebody, the flow which occurs to make a successful surgical procedure happen and at every stage, I think the company has done a phenomenal job.

I think the expertise that they have in the company in terms of having been involved in spinal cord injury before clearly shows and I think there has also been a clear increase in interest nationally after the news that came out in September. That has also helped, but I think from a company standpoint as a PI, I'm extremely pleased with the amount of infrastructure and other support that we get from the company.

<Q – Bruce D. Jackson>: All right. That's it for me. Thank you very much.

<A – Stephen L. Cartt>: Thanks, Bruce.

Operator: [Operator Instructions] And we'll take our next question from George Zavoico with JonesTrading.

<Q – George B. Zavoico>: Hi, everyone. Thank you very much and Lucas, especially to you, thank you for participating in the call and sharing your experience. Just a couple of questions, hopefully pretty quick – with regard specifically to Lucas as an individual patient, what cervical level Lucas was your injury? How much time was there between your accident and surgery? Did you get steroids? And are you seeing any continuing improvement or has the rate of improvement slowed down? Thank you.

<A>: I had a C5/C6 injury, and there were at 15 days between the initial injury and then the transplant. And then and I'm not fully sure if I have received steroids or not but going off of to Dr. Kurpad's statements, I – and since I was initially treated here, I don't believe that I did, no.

<A – Shekar Kurpad>: Lucas did not receive steroids. This is Dr. Shekar Kurpad, Lucas did not receive steroids.

<A>: As far as improvement goes, it kind of ramped up – I'd say over the first – it started after about a week and a half after the initial transplant, and it kind of really picked up over that that first – about a month thereafter, and it was real steady and it's kind of been tapering off a little bit over the last – I'd say, probably about two weeks ago, I've noticed things started to slow down a little bit but I still – to this very day, I still continue to get more strength than anything in my hands and arms. So yes...

<Q – George B. Zavoico>: I imagine a lot of that is probably due to physical therapy. Does using – being able to use your hands and arms again, it's just like it was exercise, I suppose – is that how you interpret that?

<A>: Yes, I'd say a lot of it is repetition and just doing things as – gets everything stronger every day.

<Q – George B. Zavoico>: That's great. Best of luck going forward and I hope you continue to improve. Now I have a question for – I guess for Ed or Dr. Kurpad; in terms of screening – someone asked the question about screening; what's your – number of patients you've screened, so what's your sort of dropout rate, patients that don't get into the trial, don't get dosed?

<A – Shekar Kurpad>: It's probably best from Ed – Ed's got a perspective on all the different sites in the country. So yes, the overwhelming majority of patients George, who can sense it to be in the study end up receiving OPC1. There has been a few who ended up not getting it for few different reasons, for example one individual when we did the eligibility MRI scan, it turned out they have a very severe lacerations to the spinal cord which we thought would not be amenable to OPC1 mediated repairs.

So there was another individual, for example, who after consenting the study started to have very, very rapid spontaneous return of function in his hands and fingers and felt that he was getting a sufficient amount of recovery back but he didn't want to continue and study and get OPC1. So there has been a few like that but the overwhelming majority I'd say probably between 80% to 90% who get consent – or give consent of study in depreciating OPC1.

<Q – George B. Zavoico>: That's a terrific rate. And then in terms of your number of sites you're going to be opening up. Are any other international sites, are you thinking it's not – are you thinking of going international?

<A – Edward D. Wirth>: We do have one potential site in Canada that we've been talking with – a very high profile academic institution with a very strong spinal cord injury program, but it still at very early stage, so we'll have to see if things work out. But that would – if it worked out, that would – like, would be first site outside of the U.S.

<A – Stephen L. Cartt>: Yes, George, if we progress – thinking out in the future, if we could rest the program, which we fully intend to – now we can see expanding into international sites with the next study.

<Q – George B. Zavoico>: And I presume you might need to do that, maybe release one or two sites to get EMA approval for example or Far Eastern approval; in fact is that the case from a regulatory standpoint?

<A – Stephen L. Cartt>: Yes, exactly, you got it.

<Q – George B. Zavoico>: Now to do that you also obviously have to do a Phase 2/3 trial, this is nearly dose ranging and it's getting logistics down. For the relatively rare occurrence like this, would you expect to phase, the pivotal phase 2/3 trial to be randomized or do you think – like for many other rare diseases, a single arm trial based on a comparison to historical data would be sufficient?

<A – Edward D. Wirth>: Yes, it's hard to say at this point it's really going to be driven by how strong the results might be from this study. So it's a little early to speculate at this point.

<Q – George B. Zavoico>: Okay. And the final question, real quick; what's left on the CERN Grant?

<A – Stephen L. Cartt>: Yes, so we have as of the end of the third quarter we have \$4 million rights. So the \$2.5 million that I briefly discussed, we expect to receive in the fourth quarter of this year, and then we'll have \$1.5 million that we expect to receive in 2017.

<A – Ryan Chavez>: Yes, just to be crystal clear, the \$2.5 million we expect to receive in the fourth quarter – we've already hit the milestone to receive that, so that's basically in the bag – we just need to receive it now.

<Q – George B. Zavoico>: Okay, so that's four and four – so you have about eight – you have about what \$6.3 million left after that or was it \$14.3 million originally.

<A – Stephen L. Cartt>: Yes, \$14.3 million but we received about \$10.3 million already in total, so we had \$4 million. And then we had \$2.5 million where we hit the milestone and we expect to receive that in the fourth quarter of this year. And then we have another \$1.5 million where we expect to hit that milestone in 2017 and also receive it in 2017.

<Q – George B. Zavoico>: Okay, then that will be it then.

<A – Stephen L. Cartt>: That will be it, and we're always looking at other sources of non-dilutive funding, but albeit so that's tumaround.

<Q – George B. Zavoico>: Okay, great. Thank you all very much.

Operator: We have no further questions in queue. I would like to turn the call back over to Steve Cartt for any additional or closing remarks.

<<Stephen L. Cartt, Chief Executive Officer>>

Well, thank you to everybody for joining us today, and thanks again to our special guests Lucas, in particular, and Dr. Kurpad as well. I think it's been really helpful for everybody to hear from the two of you. And we look forward to speaking with all of you in near future. Take care.
