
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): **August 23, 2011**

LANTHEUS MEDICAL IMAGING, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

333-169785
(Commission File Number)

51-0396366
(IRS Employer Identification No.)

331 Treble Cove Road, North Billerica, MA 01862
(Address of principal executive offices) (Zip code)

Registrant's telephone number, including area code: **(978) 671-8001**

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 (see General Instruction A.2. below):

- 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))
-
-
-

Item 2.02. Results of Operations and Financial Condition.

On August 23, 2011, Lantheus Medical Imaging, Inc. held a public telephone conference call and audio webcast to discuss its financial results for the quarter ended June 30, 2011. The transcript of the conference call and webcast is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description of Exhibits
99.1	Transcript of earnings release conference call on August 23, 2011

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.

LANTHEUS MEDICAL IMAGING, INC.

By: /s/ Michael P. Duffy
Name: Michael P. Duffy
Title: Vice President and General Counsel

Date: August 29, 2011

Conference Call Transcript

241435 - Q2 2011 Lantheus Medical Earnings Conference Call

Event Date/Time: Aug 23, 2011 / 08:00PM GMT

CORPORATE PARTICIPANTS

Linda Lennox

Lantheus Medical Imaging - Investor Relations

Don Kiepert

Lantheus Medical Imaging - President, CEO

Bob Gaffey

Lantheus Medical Imaging - CFO

Jeff Young

Lantheus Medical Imaging - VP Finance, Chief Accounting Officer

CONFERENCE CALL PARTICIPANTS

Kyle Smith

Jefferies - Analyst

Brian McNamara

GoldenTree - Analyst

Ray Garson

Brigade - Analyst

Jed Nussbaum

Redwood Capital - Analyst

PRESENTATION

Operator

Good afternoon, ladies and gentlemen. My name is Keith, and I will be your conference call operator today. At this time, I would like to welcome everyone to the Lantheus Medical Imaging Second Quarter 2011 Conference Call. All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question and answer session.

This call is being recorded for replay purposes. A replay of this call will be available approximately two hours after the conclusion of the live call and it will be available through August 30, 2011. You can access the replay by dialing 1-888-286-8010 and use passcode 23994821.

I would now like to turn the call over to Linda Lennox, Senior Director of Investor Relations and Corporate Communications. Linda, you may now begin.

Linda Lennox - Lantheus Medical Imaging - Investor Relations

Thank you, and good afternoon, everyone. Joining me on today's call are Don Kiepert, our President and Chief Executive Officer, Bob Gaffey, our Chief Financial Officer, and Jeff Young, our Vice President, Finance and Chief Accounting Officer.

Our remarks during this call may include some forward-looking statements, including statements related to our products, supply arrangements and clinical development timelines. Matters addressed in these statements are subject to risks and uncertainties. Such words as believe, expect, anticipate, plan, may, and similar expressions, are intended to identify such statements. Actual results may differ materially from our expectations.

Please refer to the cautionary statements and risk factors contained in our SEC filings, including our 2010 Annual Report on Form 10-K, and our most recent quarterly report on Form 10-Q filed with the SEC on August 15, 2011. Copies can be obtained at www.sec.gov, or on our website at www.lantheus.com. Except to the extent required by law, we do not undertake any obligation to update any forward-looking statements, and we caution you against relying on any forward-looking statements.

On today's call, we will also discuss certain non-GAAP financial measures with respect to our performance. We use these non-GAAP indicators for financial and operational decision-making and as a means to evaluate our performance. The definition of adjusted EBITDA is set forth in our earnings release filed as a current report on Form 8-K filed with the SEC on August 17, 2011, and is available on our website at www.lantheus.com or at www.sec.gov.

I will now turn the call over to Don Kiepert. Don?

Don Kiepert - Lantheus Medical Imaging - President, CEO

Thank you, Linda. Good afternoon, everyone, and thank you for joining us to discuss our second quarter 2011 financial and operational results.

We had a solid quarter financially. We achieved revenue growth of 10.7% over the same period last year, and adjusted EBITDA grew by over 28% year-over-year. Sales of DEFINITY grew nearly 14% over last year's second quarter. In addition, sales of TechneLite were also a strong contributor to our year-over-year results with the return of the global moly supply, despite the four-week planned NRU reactor outage in the second quarter of 2011. We also continue to maintain share with our Cardiolite and unbranded sestamibi products. Our international business has consistently performed strongly, and this quarter was no different. We continue to work toward executing on global opportunities that would significantly increase our worldwide revenue.

Having said that, the quarter was not without its operational challenges. Among other things, we continue to manage through softness in technetium demand, and a planned shutdown at Ben Venue Laboratories, or BVL, our most important contract manufacturer organization.

I'll discuss all of these topics in a moment, but first let me take you through the performance of our principal commercial products TechneLite, Cardiolite, and DEFINITY.

Starting with TechneLite, year-over-year second quarter sales grew 28% as a result of the NRU reactor in Chalk River, Ontario, coming back online in August 2010, after being out of service for 15 months, and our regaining substantial share due to our committed volume agreements. Our diversified and balanced global supply chain now includes processing facilities in Canada, South Africa, Belgium, and Australia, fed by seven separate research reactors.

This summer, the NRU reactor in Chalk River underwent a four-week scheduled inspection and maintenance shutdown. But as a result of our diversification efforts, we were able to supply approximately 80% of customer requirements for TechneLite during that shutdown.

While year-over-year second quarter sales grew sequentially, TechneLite sales were down 12% from the first quarter in 2011, largely as the result of the four-week planned maintenance shutdown of NRU. While we have expected over the past several months the TechneLite demand would return to pre-outage levels, we continue to see a prolonged industry-wide softness in demand for technetium, which we discussed with you on our first quarter call.

We continue to believe this softness is a result of a number of factors, including changes in radiopharmacy staffing and utilization practices, which allow radiopharmacies to prepare more unit doses of technetium-based radiopharmaceuticals per generator. Secondly, there's been a shift to alternative diagnostic imaging modalities during the moly shortage that has not returned to technetium-based procedures. Thirdly, an increased focus on patient radiation exposure, which we believe has led to less technetium being used per dose, and lastly, an overall decline in the MPI study market stemming from decreased levels of patient studies during the 15-month outage period that have not returned to pre-outage levels, and overall industry-wide cost containment initiatives that have resulted in a transition from free-standing imaging centers to a hospital setting.

Now, let's turn to our Cardiolite products, which include our branded Cardiolite and generic sestamibi. Second quarter sales of Cardiolite rose by 9.1% over the same quarter last year. While generic competition continues to affect us, we have diligently managed to hold onto as much share as possible. Since the first generic was introduced in September 2008, we estimate that our MPI segment share has decreased from approximately one-half to approximately one-third. We continue to believe that this solid performance in the MPI market is a result of committed volume agreements with our distribution partners, strong relationships with our distribution partners, brand awareness and loyalty within the cardiology community, and a strong safety and efficacy profile for our product. Within just the sestamibi market, we estimate that we continue to maintain approximately 45% to 50% market share.

As a result of continued softness in technetium demand and the MPI market, we initiated a series of organizational and operational changes in the second quarter to remain in a strong position for future success. After a thorough analysis comparing current and longer term market conditions with our planned business growth, we reduced our global workforce, eliminated certain open positions, and decreased other third party costs. These actions resulted in a workforce reduction of approximately 6%, with expected annual savings of approximately \$7 million. Although workforce reductions are always painful, we believe we have appropriately adjusted our operations to better align with current and future market conditions.

These organizational and operational changes allow us to continue to drive the key strategic initiatives that we believe will grow our business, including supporting our flurpiridaz F 18 program, driving sales of our marketed products, especially DEFINITY, and executing on global expansion initiatives.

Now, let's turn to DEFINITY. I'm pleased to report that DEFINITY sales continue to grow. During the second quarter, DEFINITY revenues grew almost 14% over the same period last year, and 7% over the first quarter of 2011. DEFINITY is an important diagnostic tool that provides critical patient information in a cost-effective manner, and avoids subjecting patients to other costly procedures with greater overall risk. Since its launch in 2001, DEFINITY has been administered to more than 3 million patients.

On our last quarter conference call, we reported that the FDA was reviewing our supplemental new drug application for the use of DEFINITY in stress echocardiography. We have now received a complete response letter from the FDA, which informed us that while they will likely allow further modifications to the DEFINITY label which could improve product positioning, they will not approve the use of DEFINITY in stress procedures without an additional Phase 4 clinical trial.

We're working closely with the Agency to see how much we can further modify our label and are evaluating the regulatory, clinical development, and financial implications of the FDA's response to determine what our next steps may be. We will keep you apprised of all developments on this matter.

DEFINITY continues to be the leading ultrasound contrast agent used in echocardiograms, with approximately 90% of sales in the echo contrast segment. We believe that DEFINITY has longer term growth opportunities, particularly because we have only penetrated approximately 2% of sales in the echo segment, 20% of which is believed to be suboptimal.

We utilize BVL to manufacture DEFINITY, Neurolite, and certain of our TechneLite accessories. We also rely on BVL for a majority of our Cardiolite supply. In July 2010, BVL temporarily shut down their facility in Bedford, Ohio, where they manufacture our products, among many others, in order to upgrade the facility to meet certain regulatory requirements. Prior to the shutdown, BVL manufactured for us additional inventory lots of our products to meet our expected customer needs during the anticipated shutdown period. BVL initially believed that their facility shutdown would run through March 2011. They have now indicated to us they anticipate resuming production late in the third quarter of 2011.

As a result of recent FDA inspections at BVL and our own facility in Billerica, Massachusetts, we filed a field alert with the FDA and have initiated recall activities in connection with six lots of Cardiolite and Neurolite manufactured for us by BVL prior to the shutdown. I want to emphasize that there have been no significant changes in product safety risk profiles for either Cardiolite or Neurolite, and the rates of serious adverse medical events have not changed significantly and are rare for these products. We're in the process of completing a 100% visual inspection of our existing inventory of these products to assure it meets the standard required for use. Based on those inspections, we will then determine if any additional voluntary recalls are necessary. We've also implemented a number of additional internal procedures to further enhance our quality systems. We believe that the Company's financial exposure related to this recall is low.

In addition, last week BVL announced that it will be transitioning out of the contract manufacturing business over the next few years. We have a backup manufacturer for Cardiolite, and we have active technology transfer programs for DEFINITY and our TechneLite accessories. We are currently working on a plan to ensure the expedited transfer of all of our BVL produced products to other contract sites.

Our other commercial products accounted for approximately 25% of our total product revenues in the second quarter, and include ABLAVAR, Thallium, Gallium, Neurolite, and Xenon.

We continue to believe that ABLAVAR is an important diagnostic tool for clinicians. However, market acceptance is taking significantly longer than we originally anticipated and sales have been much lower than we expected. Consequently, during the second quarter, we performed a detailed analysis of expected future sales of ABLAVAR. As a result of that analysis, we recorded charges and costs of goods sold totaling nearly \$39 million related to ABLAVAR. Bob will provide detail around those charges in a couple

of minutes. While we continue to grow sales of ABLAVAR, we do not expect any near term significant contribution from this product.

As I mentioned earlier, we continue to make excellent progress in our clinical development program, focusing in the near term on advancing flurpiridaz F 18, our PET myocardial perfusion imaging agent. We believe that if we can successfully complete our Phase 3 trials and gain FDA approval, flurpiridaz F 18 could provide physicians with improved non-invasive and cost-effective alternatives to help diagnose and evaluate cardiovascular disease. PET imaging with flurpiridaz F 18 has the potential to be a new clinical tool for the evaluation of known or suspected coronary artery disease. We believe that this agent could improve diagnostic sensitivity, which detects disease, specificity, which rules out disease, and overall prognostic accuracy.

I am pleased to report that on June 29, 2011, we initiated the first of two planned Phase 3 clinical trials to assess myocardial perfusion using PET imaging with flurpiridaz F 18 in patients with known or suspected coronary artery disease. The initiation of the Phase 3 clinical program marks a significant milestone in the development of this novel imaging agent, and reinforces our commitment to develop next generation imaging products.

The trial is the first of two planned Phase 3 clinical trials that will evaluate the diagnostic efficacy of flurpiridaz F 18, PET MPI, compared with SPECT MPI, in the detection of significant coronary artery disease. The trial is expected to enroll a total of approximately 1,350 patients at approximately 100 clinical trial sites worldwide, including sites located in the US, Canada, Europe, and South America.

During the second quarter, we presented Phase 2 study results for flurpiridaz F 18 at the International Conference of Non-Invasive Cardiology in Amsterdam, and at the Society of Nuclear Medicine Annual Meeting in San Antonio. The findings demonstrated PET myocardial perfusion imaging with flurpiridaz F 18 provided superior image quality, diagnostic certainty, and diagnostic performance for detecting coronary artery disease, compared to SPECT MPI, the current standard for the non-invasive detection of coronary artery disease. The data also demonstrated a positive safety profile for PET imaging with flurpiridaz F 18.

In addition, we continue to move forward with executing on potential partnerships for the co-development and co-commercialization of flurpiridaz F 18. We look forward to updating you on our progress.

The next two quarters will be very important for us as we continue to address our challenges and execute on our opportunities. We believe we have the resources and assets necessary to achieve sustainable financial performance and long term growth.

Now, I'd like to turn the call over to Bob Gaffey to review our financial results. Bob?

Bob Gaffey - Lantheus Medical Imaging - CFO

Thank you, Don, and good afternoon, everyone. I'll now review our business performance and financial results for the second quarter of this year. Please note that we will not provide guidance or any prospective financial information on this call.

Total revenues for the second quarter of 2011 were \$90.4 million, an increase of 10.7% over last year's second quarter revenues of \$81.7 million, but a decrease of nearly 8% from our first quarter 2011 revenues of \$98.1 million. The sequential decrease was driven by several factors that I will discuss in further detail.

Product revenue in the second quarter increased 10.8% to \$88.3 million, compared to \$79.7 million in the second quarter of last year. This increase is primarily attributable to the following three factors. First, a 27.7%, or \$6.8 million, increase in sales of our TechneLite generators, which as Don mentioned was primarily due to the return of availability of moly and regaining substantial share due to our committed volume agreements.

Second, a 13.8%, or \$2.1 million increase in sales of DEFINITY due to continued segment penetration. And, lastly, second quarter sales of our Cardiolite products increased to \$19.1, million or 9.1%, over last year's second quarter.

Although we showed good product revenue growth in the second quarter, as compared to the same period last year, our product was down nearly 8% from the first quarter of 2011. This decrease from the previous quarter is primarily attributable to the following two factors.

First, a decrease in TechneLite sales of 12.1%, largely due to the four-week scheduled shutdown of the NRU reactor, which we believe had a negative impact to sales of approximately \$3 million. In addition, we continued to experience softness in the technetium market demand that we believe is the result of the factors Don discussed earlier.

And second, a decrease in sales of Cardiolite products of 15.8%, which was primarily attributable to higher than expected sales in the first quarter due to inventory restocking. As Don mentioned, we continue to maintain a 45% to 50% market share within just the sestamibi market.

These decreases were offset by a 7% sequential increase in sales of DEFINITY resulting from our continued market penetration.

During the second quarter, our cost of goods sold was impacted by certain charges associated with ABLAVAR. Although we continue to believe that ABLAVAR has important diagnostic benefits, market acceptance has been slower than we originally anticipated and sales have been much lower than we expected.

In the second quarter, we performed an analysis of expected future sales of ABLAVAR and recorded a reserve for inventory obsolescence and a loss on our committed supply that we do not believe we will be able to sell. As a result, the Company performed an assessment of intangible assets associated with ABLAVAR and concluded that they were not recoverable. The Company, therefore, recorded a total charge of \$38.9 million.

These charges are broken down as follows a \$13.5 million inventory write-down which represents the cost of ABLAVAR finished product and API that we do not believe will be sold prior to expiration; a \$1.9 million reserve for the loss associated with a portion of the committed purchases that we do not believe we will be able to utilize prior to expiration; and a \$23.5 million intangible asset impairment charge.

Gross profit as a percentage of total revenues was 1% for the second quarter of 2011, as compared to 48% and 47% for the second quarter of 2010 and the first quarter of 2011, respectively. Excluding the \$38.9 million ABLAVAR charge, the second quarter gross profit would have been 44%. The sequential decrease in gross profit from the first quarter to the second quarter is primarily due to product mix quarter-over-quarter, as well as additional inventory reserves recorded in the second quarter related to a number of our other products.

Turning to operating expenses. Sales and marketing expenses totaled \$10.7 million in the second quarter, down \$1.1 million, or 9%, from the second quarter of last year. As a percentage of revenue, sales and marketing expenses were approximately 11.8% in the second quarter of 2011, compared to 14.4% in the second quarter of 2010. The primary reason for the decrease was the termination of our ABLAVAR contract sales force agreement in late 2010.

On a sequential basis, second quarter sales and marketing expenses were up \$1.3 million, or nearly 14%. This was primarily attributable to a reduction in stock based compensation expense recorded in the first quarter related to the expiration of an award.

General and administrative expenses for the second quarter were \$7.1 million, which is relatively flat with the second quarter of 2010, but were down approximately \$1 million, or 12.4%, as compared to the first quarter of 2011, resulting from a reduction of performance based compensation.

Turning to research and development, expenses decreased 17% to \$10.3 million in the second quarter of 2011, compared to \$12.5 million in the same period last year. This decrease in R&D expense is primarily the result of timing for clinical trial activity related to our flurpiridaz F 18 program. In the second quarter of 2010, we were finalizing our Phase 2 trial, whereas during the first half of this year, we have been in the planning and preparation stage of our Phase 3 trial.

On a sequential quarterly basis, second quarter R&D expenses were relatively flat at \$10.3 million, compared to \$10.5 million in the first quarter of 2011. Although our expenses were relatively flat in the first half of the year, we do expect R&D expenses to increase significantly throughout the remainder of this year as the result of the initiation of Phase 3 flurpiridaz F 18 trial with the enrollment of our first patient in late June.

We continue to make investments in our pipeline because we believe that products such as flurpiridaz F 18 will be key value drivers for the Company in the future. We are considering a number of options to advance these programs, including potential partnering opportunities.

Other expenses, which include interest expense and the amortization preferred financing costs, was \$10 million for the three months ended June 30, 2011, an increase of \$2.8 million over the same period last year. This increase is primarily related to the issuance of our senior notes.

The benefit for income taxes increased \$14.9 million due to the recognition of additional deferred taxes based on the loss that we incurred during the second quarter of this year, primarily as a result of the impairment charge and the inventory write-down associated with ABLAVAR.

Now, I'll walk through the second quarter adjusted EBITDA calculation beginning with the second quarter net loss of \$22.3 million. We add back \$10.4 million of net interest expense, which includes approximately \$600,000 of amortization for deferred financing costs, and \$9 million of depreciation and amortization, which includes \$100,000 related to the accretion of our asset retirement obligation.

These add-backs are offset by a benefit for income taxes of \$15.1 million, which excludes the effect of the Bristol-Myers Squibb indemnification income of approximately \$400,000.

We then add back the following adjustments \$38 million of asset write-offs associated with the impairment of ABLAVAR intangible asset and the inventory write-down of ABLAVAR and other products; \$1.9 million associated with the loss on ABLAVAR purchase commitments; severance of \$1.6 million associated with the June reductions; and approximately \$400,000 sponsor fees and other expenses.

These add-backs are offset by a reduction for non-cash stock based compensation benefit of approximately \$500,000.

The cumulative affect of these adjustments results in adjusted EBITDA of \$23.3 million for the second quarter of 2011, a 28.2% increase from the second quarter last year, and a 13.6% decrease from the first quarter of 2011. This decrease is primarily the result of a benefit recorded in the first quarter of 2011 due to the restocking of Cardiolite and the negative impact on TechneLite in the second quarter of 2011 due to the four-week NRU shutdown.

Turning to the balance sheet, capital expenditures for the three month period ended June 30, 2011 were \$1.2 million, compared with \$4 million for the period ended March 31, 2011. We continue to plan for capital expenditures to be in the range of \$10 million for the year.

Our inventory on hand was \$33 million in the second quarter, compared to \$43.1 million in the previous quarter. The primary reason for this decrease relates to the inventory write-down associated with our ABLAVAR product.

As we have discussed in the past, we have an inventory supply agreement with Covidien for ABLAVAR, which has minimum quarterly purchase commitments. Under our contract, we are required to continue to build inventory during this commitment period which runs through September of 2012. We are currently in discussions with Covidien regarding these manufacturing commitments. Therefore, the amount of the inventory build and the length of the commitment period will depend on the results of our negotiations with Covidien. We will keep you apprised of our progress on this front.

Finally, cash and cash-equivalents as of June 30, 2011 were \$27.8 million, down \$10.2 million from the previous quarter, primarily as a result of our debt service payment which we made in May.

This concludes our financial review. I'll return the call back to Don for final comments.

Don Kiepert - Lantheus Medical Imaging - President, CEO

Thanks, Bob. Our performance in the second quarter of 2011 was solid. As we move to the third and fourth quarters, we face several operational challenges. Those of you who know us well know that since we became an independent company in 2008 we have faced numerous challenges and have overcome each and every one of them, from the DEFINITY box warning, to the Cardiolite generic event, to the 15-month moly supply shortage.

We believe we will overcome our current challenges, as well. We have a robust portfolio of leading medical imaging products on the market, along with a promising pipeline in development. We are dedicated to the future of diagnostic medical imaging and developing new tools for the diagnosis and management of disease. And we remain focused on continued strong financial performance, both in the coming quarters and the years ahead.

Thank you again for joining us today. Thank you for your continued support. And now we'd be happy to take your questions. Operator, please open the lines for Q&A.

QUESTION AND ANSWER

Operator

(Operator Instructions)

Your first question is from Kyle Smith with Jefferies. Please proceed.

Kyle Smith - Jefferies - Analyst

Hi. Good afternoon, everyone, and thank you for those remarks — very helpful color there. I did have a couple of questions. First, on the recall, Don, you said that you believe that your financial exposure is low. I'm just curious what the basis for that is?

Do you have a good read now into how many vials you actually expect to be returned? What the dollar value of those would be? And can you tell us a little bit about how the moving parts work with respect to financial impact to you versus BVL versus insurance claims?

Don Kiepert - Lantheus Medical Imaging - President, CEO

Sure. Be happy to do that. Bob's been working on this — we've both been working on it. The reason that I said that we believe that our financial exposure is low is because when we initiated the recall, we were unaware at the time how many vials were actually in the field from the lots that were recalled. Today we know that the number of vials is extremely low, and consequently, that's why we believe that the financial risk would be low.

The typical approach that a company takes when there's a recall is in the event that vials are out there that have been recalled, customers return those and we typically replenish their supply. And then with BVL, the normal course of action would be reimbursement to us for our cost of goods sold and any related costs associated with the recall. That's the typical way to handle it.

But what we know today — and that's part of the reason why we wanted to delay the call a week was to get better insight into how many vials might be on the market of those recalled lots — we feel confident that the number of vials was de minimis and the financial impact would be low, consequently.

You want to talk about the insurance side, either Bob or Jeff?

Bob Gaffey – Lantheus Medical Imaging - CFO

Let me first put a little color on this. We have certainly stronger information with regard to the US and North America market, so I think Don's comments are right on point.

What we've learned to-date is that there's minimal inventory that has not been exhausted in those marketplaces, and there's limited inventory in the international markets which we're still in the process of actually getting feedback from. So, that will take a little bit longer, which is why we don't have a complete financial picture of it. But we certainly believe that it is low.

And in terms of an insurance claim, we don't normally give public disclosure on insurance policies, but we believe we have adequate insurance coverage. And to-date we have, in fact, informed and provided notice of claim to our carrier Zurich, which, by the way, is the same carrier in our business interruption claim related to the NRU outage.

We have not yet quantified the Zurich loss arising in connection with BVL matter. And we do not know that at this point in time as we are still conducting the investigation.

Kyle Smith - Jefferies - Analyst

Great. But it does sound like overall the impact should be very much contained, which is reassuring and good to hear.

What about in terms of reputation impact? One of the strengths of the Company, I think, is the high standing and high regard that your various products are held in by the market. Is there any repercussion on that front that has you concerned with respect to Cardiolite?

Don Kiepert – *Lantheus Medical Imaging - CEO*

I don't believe so, Kyle. This brand has been out there since 1991, and well respected. And I think that pharmaceutical companies that look at these issues conservatively are well respected. And safety is always the number one consideration on an issue like this. So, we've not gotten any negative feedback from our customers.

I would add prospectively that we have agreements on committed volume with both Cardinal, and a large percent of the independent pharmacies that make up UPPI. So, I think generally speaking, pharmacists understand that recalls can happen. And I don't believe it'll be a black cloud over the Cardiolite brand.

Kyle Smith - *Jefferies - Analyst*

Great. That's also good to hear. And then turning to the other perspective concern — the BVL shutdown. I was wondering if you could explain to us a little bit what your contingency planning is if there are further delays in the restart of that facility. I know they supply, I think, 100% of your Neurolite and DEFINITY and a good portion of your Cardiolite. If you could just help us understand what potential risk might be there, that would be helpful.

Don Kiepert – *Lantheus Medical Imaging - CEO*

Maybe I could start with kind of a status report on where BVL is on their return to service program. As you can imagine, they have been collaborating very closely with the FDA throughout this whole process. And for them to begin manufacturing, the FDA needs to confirm satisfactory GMP status.

BVL has launched, on Friday, the last phase of their facility qualification, which is a two-week phase. It's actually a media fill process. As a result of that, we expect the facility to resume operation by the end of next month.

We're on top of this. We have a few people in our technical and quality teams who are actually stationed there and are working closely with BVL. We've gotten our products prioritized for manufacturing by them. And we're working toward a rapid and flawless restart. Following product pre-qualification and FDA approval, we expect to begin shipping product from BVL — new product from BVL in the fourth quarter.

Now, what we've done — you're accurate in your summary. We have a second manufacturer of Cardiolite. Actually, they've begun manufacturing a lot today. And that won't be available, we believe, until early fourth quarter, if not sooner. We also have on our TechneLite accessories identified another company who can provide us with the evacuated vials and also the saline.

And, as it relates to DEFINITY, we have inventory to last to the end of this calendar year. We think that it is unlikely that DEFINITY would be adversely affected given the timeline that BVL is communicating to us.

Neurolite — we need to find another supplier. Our only manufacturer of Neurolite is currently BVL. So, that'll be a to do, especially in the context of BVL's decision to exit the CMO business within the next three or several years. It's likely to be two-and-a-half to three years out.

So, that's kind of where we are, Kyle. I hope that answers your question.

Kyle Smith - *Jefferies - Analyst*

That's helpful. And best of luck with the flawless process over these final few weeks with BVL. Last question before I hope back in the queue is on the ABLAVAR front. I notice that \$1.3 million of the ABLAVAR inventory is being held in current assets.

And I was just curious if we should use that as a good indicator of your expected cost of sales related to ABLAVAR over the next 12 months, and then maybe ratchet the number up a bit to get an expected sales number? Is that a fair way of looking at that?

Jeff Young - Lantheus Medical Imaging - VP Finance, Chief Accounting Officer

Kyle, this is Jeff. I think that as required, the current ABLAVAR number would be the expectation for the inventory utilized in the next 12 months.

Kyle Smith - Jefferies - Analyst

Okay. And fair to assume that that's a pretty high gross margin — 80% to 90% maybe even higher?

Jeff Young - Lantheus Medical Imaging - VP Finance, Chief Accounting Officer

No, that's not correct. The product for ABLAVAR, as it currently stands, is a lower margin product.

Kyle Smith - Jefferies - Analyst

Okay. That's very helpful. Thank you. I'll hop back in queue.

Operator

Next question is from the line of Brian McNamara with GoldenTree. Please proceed.

Brian McNamara - GoldenTree - Analyst

Hey. Thanks for taking the questions. First, is on the recall. Were all the Cardiolite lots affected manufactured by BVL, or were some of them manufactured as well by Manati?

Bob Gaffey - Lantheus Medical Imaging - CFO

No, Brian. They were all manufactured at BVL.

Brian McNamara - GoldenTree - Analyst

Okay. And I think we've talked about this in the past, but can you confirm that Manati has sufficient capacity to meet all of your North America needs if BVL were not able to resume manufacturing of Cardiolite.

Don Kiepert - Lantheus Medical Imaging - CEO

No, they do not, Brian. They have been a minority supplier of Cardiolite and they do not have the capacity to service the whole North American market.

Brian McNamara - GoldenTree - Analyst

What percentage of your demand for North America could they meet?

Bob Gaffey - *Lantheus Medical Imaging - CFO*

That's difficult at the moment to assess, Brian, because really that depends on us working with that facility and gaining a run time, if you will. So we are in discussions with them today in terms of how much more they could help service us. But today we can't really help you answer that question until we've had further discussions.

Brian McNamara - *GoldenTree - Analyst*

Okay. Currently, what percentage of your North American Cardiolite needs were they supplying in ordinary course when BVL was also supplying it? It's somewhere less than 50%. Is it 25%, or is it less than that?

Don Kiepert - *Lantheus Medical Imaging - President, CEO*

It's a small percent, less than 25%.

Brian McNamara - *GoldenTree - Analyst*

Okay. And is your cost out of them the same as it is BVL, or do you pay more for Manati, and do you expect to pay more if you have to get more run time?

Bob Gaffey - *Lantheus Medical Imaging - CFO*

It's slightly higher.

Brian McNamara - *GoldenTree - Analyst*

Slightly higher today, but could go higher if you needed more run time?

Bob Gaffey - *Lantheus Medical Imaging - CFO*

No. I don't know if that's the case. I think it's a matter of priorities at that manufacturing facility or about what their needs are, meeting their other customer needs and their own needs.

Don Kiepert - *Lantheus Medical Imaging - President, CEO*

Brian, I don't believe if we bought more from Manati that that would create a significant financial impact on a gross margin basis.

Brian McNamara - *GoldenTree - Analyst*

Okay. And then you made comment that even once BVL is back up and running you might be prohibited from marketing the product out of BVL in some countries. Can you just elaborate on what that means and what geographies, particularly, and what needs to happen for you to be able to market those products there?

Don Kiepert - *Lantheus Medical Imaging - President, CEO*

Yes. Well, typically what happens when the FDA confirms satisfactory GMP status, which is a submission that BVL makes, they would typically make a submission to the European regulatory agencies at the same time for GMP status confirmation. And so, those kind of go hand in hand together.

Currently, the products that are manufactured by BVL that are distributed in Europe are being able to be sold if it's considered to be medically necessary. So, what we have done is we've initiated letters to the regulatory agencies with an explanation on why these products are medically necessary. And where we've heard back from some; we've not heard back from all of them.

The ideal scenario would be if the FDA grants — confirms a satisfactory GMP status for BVL, then coincidental to that, the EMEA would do the same. And then any other regulatory agencies there. If they don't do that, then we'd be working through advancing a compelling argument for the medical necessity factor for the use of these products.

As it relates to Japan, which we have a strong working relation with Fuji Film, we are not being impacted by the same type of medical necessity requirements that happening in Europe.

So, I hope that answers your question, Brian.

Brian McNamara - GoldenTree - Analyst

Yes. I guess maybe just a follow-up on that. If I understand this correctly, you've outlined earlier in the call what's required in order for you to get the facility back on line with the FDA to start manufacturing. Once that happens, you'll have the green light to market and sell product in the US, and then does that extend to Canada as well?

Don Kiepert - Lantheus Medical Imaging - CEO

Canada has Health Canada and we have been successful in securing medical necessity necessary code. So, our products are identified —Neurolite, DEFINITY and Cardiolite — as being medically necessary. So, we're able to distribute those products in Canada. Now, I would expect that once the FDA, again, confirms GMP status that Health Canada would look at that, and hopefully, would move in that direction also. But we were still proactive in getting that done.

Brian McNamara - GoldenTree - Analyst

So, the optimistic look at this is that EMEA and Canadian authorities will piggy back on the FDA GMP certification. Absent that, you've got to rely on medical necessity exceptions in those geographies, but you'll have the green light in the US provided you get it at FDA.

Don Kiepert - Lantheus Medical Imaging - CEO

That's correct. But I would add one more point. In Canada, we've already secured the medical necessary code and classification.

Brian McNamara - GoldenTree - Analyst

All right. And then, just finally one question on cash flow, for the moment. You brought your payables and your accrued expenses down quite a bit. There was a big drain on cash flow. Was there something unusual there, or do you expect to reverse in the third quarter?

Jeff Young - Lantheus Medical Imaging - VP Finance, Chief Accounting Officer

This is Jeff. I think you will see some reversal in those numbers. On the accrued piece, the biggest driver of that was approximately \$11 million reduction in the accruals, principally related to the accrued interest, offset by the severance as well as that lost contract reserve.

In the payables, what you're seeing is principally related to a number of factors. One is just the reduction as a result of the Nordion outage in our overall costs. So you will see that bounce back.

Brian McNamara - GoldenTree - Analyst

Got it. Thanks. I appreciate it.

Don Kiepert – Lantheus Medical Imaging - CEO

Anything else, Brian?

Brian McNamara - GoldenTree - Analyst

No. Thank you.

Operator

Your next question is from the line of Ray Garson with Brigade.

Ray Garson - Brigade - Analyst

I just have a couple more follow-ups on the BVL kind of manufacturing shut-down. As it relates to the third quarter, do you feel as though you have sufficient supplies to meet the market demand?

Or, is the point that the third quarter results are going to be impacted by the lack of supply, and then depending on how the FDA and the other agencies respond then you can kind of begin meeting the needs of the market again in the fourth quarter? I just want to make sure I fully grasp exactly the sequencing of events here.

Don Kiepert – Lantheus Medical Imaging – President, CEO

Yes. What we have decided to do, we have so many lots that we have here — some retained vials from lots that are on the market. We have other lots that could be distributed in the market. We felt it was prudent to institute a 100% visual inspection on the vials and we're in the process of doing that. And it's really too early to say, but we will be looking at every vial.

And based on what we find from a particular matter viewpoint will determine whether or not we hold any other lots, if you will. I can't give you any more of an update than that at this point because we're actually in the process of visually inspecting all of these vials.

When you think about BVL, though, you're correct. A new manufacturing product of BVL and Manati would likely be available in the fourth quarter. We have the month of September, obviously, that we want to supply Cardiolite and other products during. DEFINITY we have inventory until the end of the year. And with Cardiolite, depending on how the 100% visual inspection goes, that will determine what we're able to do in September.

Ray Garson - Brigade - Analyst

Okay. And as it relates to the BVL process again, you said they started the final validation process, I think you said last week. And you expected them — do they have a scheduled appointment with the FDA that you guys have visibility around?

Or, is it one of these things where once they complete that validation process then they have to wait for the FDA to come back to them and see them when it fits with their schedule? Maybe we just tighten up some of exact dates a little.

Don Kiepert – Lantheus Medical Imaging – President, CEO

Yes, basically, it's an estimated two-week process. And this is the final step before restart. They then are likely to file a CBE-30, which means that they're going to start manufacturing but they give notice to the FDA. If the FDA has an issue with that, they will come back and talk to BVL. But BVL has been collaborating with the FDA on an ongoing basis.

So, there's constant dialogue with them. So, once this final step is done, they file the CBE-30. They would then be able to begin manufacturing. The FDA could choose to come back and say we're not going to grant GMP status. But because of this constant communication with the FDA and we have people there so we know what's going on — I think would be — it's possible, but unlikely.

Ray Garson - Brigade - Analyst

Okay. So, it doesn't require an incremental inspection from the FDA. It would just be basically they send notice to the FDA and if the FDA has an issue, then they could delay it further. But they don't have to wait for anybody to show up and physically walk anything. Correct?

Don Kiepert - Lantheus Medical Imaging - President, CEO

That's correct.

Ray Garson - Brigade - Analyst

Okay. And then, you also mentioned that BVL has indicated that they want to get out of the contract manufacturing business. So, in the Q it talks about some potential for some claims against them as it relates to the recall. Given that backdrop, do you feel like they're taking this matter as seriously as I hope you guys are imparting on them that they should?

And, do you really feel like you have any financial recourse back to them as it relates to recall or any other matters as a result of kind of some of their missteps here on the manufacturing side?

Don Kiepert - Lantheus Medical Imaging - President, CEO

Well, first let me just say, BVL is owned by Boehringer Ingelheim. And the trip that I made to meet with the president of BVL, the head of manufacturing for Boehringer Ingelheim was there. They have a contractual commitment to us to continue to supply us for a period of time. And they're the largest lyophilization manufacturer in North America.

So, there's lots of products that — 72% of all the products that they make are sole sourced of BVL. So, there's going to be a real push on the part of the FDA and the Office of Drug Supply to make sure that they do not abruptly exit from a manufacturing viewpoint.

And so, we believe that we have the time. We have already started that process on DEFINITY. We have a backup for Cardiolite in our secondary manufacturer. We'll need to find another one to be more of a primary. We'll need to do the same with Neurolite. The Technelite ancillary supplies we've already sourced — we have an alternate supply on that.

And then the other products that we have don't come from BVL. All the hot products we manufacture. ABLAVAR is manufactured by another CMO. So, we're going to diligently stay on top of this tech transfer process to make sure that we will not be at risk from a product supply viewpoint because of BVL's decision to exit this market.

Ray Garson - Brigade - Analyst

Have you guys started to talk about any sort of financial restitution as it relates to some of these things? Or, is that still kind of too early at this point?

Don Kiepert - Lantheus Medical Imaging - President, CEO

Well, what we've done is we've provided a notice of a claim to our carrier, Zurich, which is the same carrier that Bob mentioned that we have the business interruption claim related to the NRU outage, which we identified in previous quarterly reports.

We've not yet quantified the loss because we're still in the middle of the process. But we've gone on notice to say that this is something that we're taking very seriously. We need more information before we could determine what claim, if any — what the claim might be, if any.

Ray Garson - *Brigade - Analyst*

Okay. But it's to your insurance provider at this point where you're focusing your efforts.

Don Kiepert - *Lantheus Medical Imaging - President, CEO*

Yes.

Ray Garson - *Brigade - Analyst*

In terms of the NRU outage and that business interruption, is there any update in that process in terms of the potential for any — for that to be resolved?

Don Kiepert - *Lantheus Medical Imaging - President, CEO*

Well, that's something that we typically don't give guidance on, as you can imagine. We're in the middle — there's a lot of back and forth on the whole thing. So we can't give guidance on it, except that the process is moving forward.

Ray Garson - *Brigade - Analyst*

Okay. And then, you'd also mentioned with respect to — maybe Bob did — with respect to R&D and kind of getting folks prepared for the ramp in the second half of the year. I recognize there's limits on guidance, but can you kind of help put that into some perspective just given some of these other kind of issues that are going on that we want to make sure that we properly capture that ramp?

Bob Gaffey - *Lantheus Medical Imaging - CFO*

It is difficult to give you guidance even from a planning perspective. It's really based on, in large part, on patient enrollment and how quickly that enrolls — that Phase 3 trial. I think previously we've talked about what it costs on a per patient basis and there's some other additional costs associated with the program.

We are expecting that — we have an enrollment curve, but it's really early in the game. We're really just getting those sites up and running now. So, that takes a little bit of time before you actually get a smooth run rate. So, it's really too early to give you some sense as to what that might look like.

Don Kiepert - *Lantheus Medical Imaging - President, CEO*

But what we said and what Bob said is accurate. You would expect when you're in a Phase 3 program that your R&D costs are going up. And the reason we're willing to do that is because the value of the asset once launched, we think, could be significant. But we will manage that appropriately as we have in the past.

And importantly, we're looking to find co-distribution partners, co-development partners, who might want to partner with us and help offset some of that investment. It's too early to call when it might happen and how much it might be. But I want you to know that we're aggressively pursuing those discussions.

Ray Garson - Brigade - Analyst

Okay. All right. So it sounds like maybe the fourth quarter you might start to have a little bit. When those numbers come out we'll get a little better perspective for the build up of that cost as the patient enrollment numbers get a little bit more —

Bob Gaffey – Lantheus Medical Imaging - CFO

I think that's right.

Don Kiepert – Lantheus Medical Imaging – President, CEO

That's a good way to look at it.

Ray Garson - Brigade - Analyst

All right. And then the final thing I had was just with respect to the Covidien contract, you mentioned kind of beginning some negotiations there. I'm just kind of — what really are the options that you have other than — are there any outs in this contract at all with respect to —?

Bob Gaffey – Lantheus Medical Imaging - CFO

I can't speak to that. I think we're having some good dialogue with Covidien, and that's about all I can say at this point in time. We've been in discussion with them for a short period of time, relatively speaking. They're open to those discussions, and that's about all I can tell you at this point.

Don Kiepert – Lantheus Medical Imaging – President, CEO

And as we progress that, we will update you. We will absolutely update you as this progresses.

Ray Garson - Brigade - Analyst

All right. Thanks so much.

Bob Gaffey – Lantheus Medical Imaging - CFO

Thank you.

Operator

Okay. We have one more question. It's from the line of Jed Nussbaum with Redwood Capital. Please, go ahead.

Jed Nussbaum - Redwood Capital - Analyst

Hi, good afternoon. Thanks for all the fulsome discussion. Just for starters, can you just remind us what your guidance has been on rough cost per patient for the F 18 clinical trial?

Don Kiepert — Lantheus Medical Imaging — President, CEO

Well, we have —there's two elements — there's really three elements of cost. One is the site cost, which is about \$15,000 per patient, which we have given you guidance on previously. The other cost is we have various CROs that we work with and we have to pay them. And then we have internal expense.

So, the number that we've given is the one what we would be willing to share at this point. That's about \$15,000 per patient for the site payment. But that's not the total payment because you have to cost out everything else to go along with that.

Jed Nussbaum - Redwood Capital - Analyst

Okay. I mean, order of magnitude should I expect that the other two costs would double the cost of the site? I'm just trying to — this gets in to your internal planning but I'm just trying to get a feel for whether you're talking about a \$40 million cost, or a 25, or a 50 or —?

Bob Gaffey – Lantheus Medical Imaging - CFO

I think if you'll look at our run rate, that's supporting most of the internal expense that we have today. As Don mentioned, the 15 per patient you'll see that begin to move, depending on how quickly the patient enrollment occurs. And there are some similar associated costs that we haven't really disclosed in any clearer detail than that. It's not a substantial portion. I think we've given clarity to it as much as we can.

Don Kiepert – Lantheus Medical Imaging – President, CEO

In R&D there are other costs. We have low spending on a C&A program, our second pipeline product. We're not investing a lot there. And we have — there's a team there that's working on getting all of these sites qualified because we'll have — we have multiple PET manufacturing sites because of the half life of F18.

So, we have an internal team that's part of that Flurpiridaz development process that's out qualifying sites and providing oversight for that. We don't want to — really be vague, but this is kind of the way that we positioned it from what we can say at this point.

Jed Nussbaum - Redwood Capital - Analyst

Okay. Sure. And then, as it relates to the inventory issues, I understand that there's still this question as to how the visual inspection of the vials will turn out. But I'm wondering if you could just bracket — in the upside case that things go as planned with BVL and they're beginning to ramp up production at the end of September — what the impact you'd expect to be to your sales or some bracket, depending on the inspection of vials for the third and fourth quarter?

Don Kiepert – Lantheus Medical Imaging – President, CEO

I don't have that information myself because we're in the middle of doing it. We have two shifts doing it, by the way, and it's a top priority. But I can't really give you any suggested range on that at this point.

Jed Nussbaum - Redwood Capital - Analyst

Okay. Thanks. We'll just wait for the next quarter.

Don Kiepert – Lantheus Medical Imaging – President, CEO

Are there any other questions?

Operator

Yes. You have a follow-up from the line of Kyle Smith with Jefferies. Please, go ahead.

Kyle Smith - Jefferies - Analyst

Yes. Hi, guys. Thanks for the follow-up. You mentioned there the costs on you're running two shifts doing the visual inspection of the vials. Should we be thinking of these as incremental costs that are going to flow through and impact your gross margin? Are they things that you would itemize out and treat as EBITDA add backs? Are these costs just sort of absorbed into your existing infrastructure? How should we be thinking about those?

Bob Gaffey – Lantheus Medical Imaging - CFO

It's relatively small in terms of our contract relationship with BVL. We believe those are recoverable.

Kyle Smith - Jefferies - Analyst

Okay. In terms of the impact from the savings that you mentioned — the \$7 million of savings annualized. Is that something that should show up right away? And can you give us a little color on what parts of the organization that came out of?

Bob Gaffey – Lantheus Medical Imaging - CFO

It came across the — most parts of the organization. So you'll see it across from manufacturing to R&D, even into sales and marketing, a little bit in G&A. It was broad based. You should see that begin to be reflected in the next quarter.

Kyle Smith - Jefferies - Analyst

And then, last item for me. On the R&D, I know it was sort of well-discussed here. Just to be clear, since you're talking about being in the early stages of the ramp, we should be seeing most of the second half increase in the fourth quarter and a relatively small delta from 2Q to 3Q. Correct?

Don Kiepert – Lantheus Medical Imaging — President, CEO

That's an accurate way of looking at it.

Kyle Smith - Jefferies - Analyst

Okay. Great. Thank you for all the answers, gentlemen. Much appreciated.

Don Kiepert – Lantheus Medical Imaging – President, CEO

Thank you all for all of your support. Is there another question?

Operator

We do — we have one more follow-up from the line of Brian McNamara with GoldenTree. Please, go ahead.

Brian McNamara - GoldenTree - Analyst

Just a couple of follow-ups. On the visual inspection, you've recalled six lots that were in the field. Has the visual inspection identified any other product that will not be shipped?

Don Kiepert - *Lantheus Medical Imaging - President, CEO*

Let me explain what we would do. The process — just so you'll understand, Brian. If we identify that there is a particulate matter — particle — we then would characterize it. We then would do a medical assessment by our medical team. And then our quality assurance group would look at that assessment and determine whether there's an issue.

But it's a multi-step process that we go through, and we're in the middle of doing that as we go here. So, I can't give you any more guidance on that except that's the process that we follow.

Brian McNamara - *GoldenTree - Analyst*

Okay. But, I guess, have you identified any product with particulate that has then entered that process?

Bob Gaffey - *Lantheus Medical Imaging - CFO*

Brian, the process, again, is ongoing. We haven't concluded anything about any other lot at this point in time. So, of all the lots and material that we have, we have not come to a conclusion on any of those lots, as the process takes a fair amount of time to go through the full product assessment.

There is nothing more that we can tell you about that process that we're going through. It should take — it will take a few weeks of time to complete. It does take quite a bit of time to go through visual inspection and go through the steps that Don just mentioned to you.

Brian McNamara - *GoldenTree - Analyst*

Okay. And so, has any — where I'm going with this also is can you give us a number of like a third of what we have on hand has been given a clean bill of health, or that can't be determined at this point?

Don Kiepert - *Lantheus Medical Imaging - President, CEO*

That can't be determined.

Brian McNamara - *GoldenTree - Analyst*

Okay. All right. Thank you.

Don Kiepert - *Lantheus Medical Imaging - President, CEO*

All right, Brian. Thank you.

Operator

Gentlemen, there are no other questions.

Don Kiepert - *Lantheus Medical Imaging - President, CEO*

All right. Thank you all for your support. We will keep you posted.

Bob Gaffey - *Lantheus Medical Imaging - CFO*

Thank you.

Jeff Young – *Lantheus Medical Imaging – VP, Finance, Chief Accounting Officer*

Thanks, everyone.

Don Kiepert – *Lantheus Medical Imaging - CEO*

Take care.

Operator

Ladies and gentlemen, that concludes today's conference. Thank you, for joining us, and you may now disconnect. Everyone have a great day.