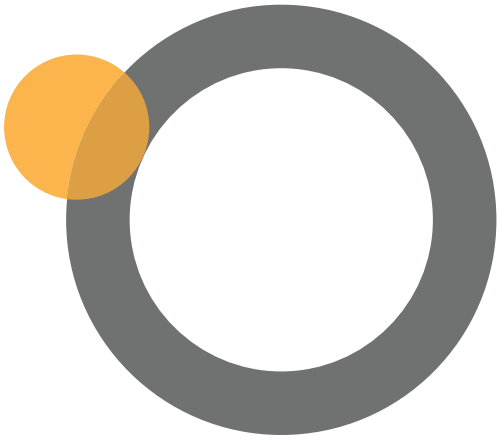

ONCOSEC™

IN THE NEWS

Los Angeles Times

Op-Ed

'I have terminal cancer. And I'm dying in a yearish.'

Mt. Diablo is silhouetted as the sun rises above the Sacramento River delta. (Los Angeles Times)

By Melinda Welsh

DECEMBER 11, 2015, 7:34 PM

The enormity of the news didn't sink in fully, not at first, even after my doctor uttered the words: "I'm sorry, we did find cancer." My husband, Dave, and I had only the faintest sense that evening that our lives had been hijacked forever.

Early 2014 brought major surgery, then six weeks of chemotherapy and radiation. Eight months later they found cancer again, so it was Christmas surgery and more of the same. When a scan in June showed new tumors, the outlook turned bleak. The cancer, a rare type — metastatic squamous cell head and neck carcinoma of unknown primary — had gone systemic.

Like all doctors, oncologists want to offer patients hope — who can blame them? But with a little prodding, I was able to learn the approximate truth. A Stanford specialist gave me six to nine months to live. "But there are people who do a lot better," he said. My surgeon told me "Months to a year." My UC San Francisco oncologist said, "The average is a yearish, but nobody's average."

So there it is. I'm 59. I have terminal cancer. And I'm dying in a yearish.

I feel perversely well right now. I have recovered from the worst side effects of treatment, and I am not yet experiencing the corporeal failure that is to come. I am working part time. And I have turned my attention to the question How do I best spend the time I have left?

My answer is writing, family and friends, the pleasures of small things.

My sister and brothers and the rest of our clan gathered for a reunion on the Monterey coast this summer. My niece came over from France, bringing her young daughter and new baby. We sobbed quietly in each other's arms as farewells were said, both knowing we'd likely never see each other again.

I crossed the boundary into hospitals, clinics, chemo infusion rooms, scanning stations and radiation lobbies. I met my fellow travelers, the

rail-thin man in the corner with the clogged IV, the elderly woman in the stunning purple hat waiting for her turn on the radiation table, the state bureaucrat who took his chemo wearing a tie, the university student who arrived at the infusion center in a taxi. The solidarity I feel with the other cancer patients is almost overwhelming. Like me, they probably weren't aware this "night side" even existed until they arrived in it.

I've told my skilled and caring doctors that I want no "maintenance chemotherapy." For me, the possible benefi t isn't worth the downside. I am a "do not resuscitate" person — desperate to go on living but against prolonging my dying once that process is in full swing.

My new oncologist, a research scientist doing cutting-edge work in personalized medicine, is trying to get me into clinical trials that don't come replete with debilitating side effects. I've started gene therapy — injections of pIL-12 with electroporation — that has shown promise in other patients. If I'm fortunate and push hard enough, I might also get access to the immunotherapy drug pembrolizumab, though it is not yet FDA-approved for my type of cancer. Any of these might net me more time before the decline, and boy, would I take that time.

Still, my basic trajectory is unswerving. I sometimes worry about my ability to exit life with grace and humor. What if I'm bad at suffering? I admit I can fi ll up with fear, but what's the point? For counsel, I turn to my favorite philosopher, Lao Tzu: Be content with what you have/rejoice in the way things are/When you realize there is nothing lacking/ the whole world belongs to you.

I understand that my infinitesimally tiny piece in all this is coming to a close. Letting go will be diffi cult, but death has its own clock. So I will take solace in the idea that, once gone, I may come to occupy a small space in the hearts of the people who loved me most. And perhaps from there, I will be a source of a few simple reminders: Time is limited. Life is miraculous. And we are beautiful.

Dave booked us a cruise to Alaska, and we're planning a few other special trips. But mostly we read and laugh. We work. We walk and watch movies. I was told "Don't skip dessert" — so we don't. We play the Neville Brothers and dance around the living room. We've taken to getting up early a a week and driving out to see the sunrise over the fl atlands of our mostly rural county. Our dog Scout thrusts her head out the window from the back seat, passionate on behalf of the here and now. I am suddenly aware of how differently the sun announces itself into the world each day.

In her famous essay "Illness as Metaphor," Susan Sontag wrote about "the night side of life," a kind of parallel universe that opens up when a person moves from the kingdom of the well into that of the sick. I didn't know it right away, but I immigrated to that new place the moment I was diagnosed with cancer.

Melinda Welsh was founding editor of the Sacramento News & Review. She is leading a national writing project about climate change, www.letterstothefuture.org

Los Angeles Times

Op-Ed I have terminal cancer and I know my friends want to ask, 'Aren't you dead yet?'

Sunrise near Eads, Colorado, on June 29 (Los Angeles Times)

By Melinda Welsh

JULY 17, 2016, 5:00 AM

Last December I wrote an essay for The Times about what I wanted to do with my life after I was diagnosed with terminal cancer. In July of 2015 — despite multiple surgeries, rounds of radiation, and chemotherapy — three doctors had given me and my husband their bleak perspectives on how much time I had left: "six to nine months," "months to a year," "a yearish."

In the weeks that followed my public coming out about the grim news, a benevolent tidal wave of comments and emails washed over me from friends, co-workers and many thousands of strangers. Now when I run into friends on the streets of my town, they hug me and tell me I look great. But I can see it in their eyes; what they really want to say is, "Aren't you dead yet?"

Well, no. As it turns out, I became a terminal cancer patient at a time of sea change in research on the disease. As Siddhartha Mukherjee, oncologist and author of the Pulitzer Prize-winning "Emperor of All Maladies," puts it, cancer care has entered a "mapless moment" for doctors and their patients.

To that I am living proof. I thought I'd be gone by the end of this summer, but now my calendar has lengthened in ways my doctors couldn't have imagined even a year ago. For obvious reasons, I'm a devotee of living fully in the present, but recently I've been allowing myself to imagine a future too: a 60th birthday this fall, another Christmas, maybe more.

What changed? Genome-sequencing technologies and immunotherapy — a new set of medicines that help patients like me use our bodies' natural defenses to fight cancer. These treatments simply didn't exist a few years ago. Unlike chemotherapy and other standard approaches, the breakthroughs tend to produce few crushing side effects. The poster child for immunotherapy is former President Jimmy Carter, who was given a terminal diagnosis when melanoma metastasized to his liver and brain in 2015. He underwent treatment, and

around three months later, his cancer had made an astonishing full retreat.

My cancer has backed away too. Under the care of oncologist Dr. Alain Algazi, a skin cancer specialist and research scientist at UC San Francisco, my treatment consists of two parts. The firstinvolves a clinical trial with an experimental gene therapy regimen. Since the fall I have been getting injections of the genetic material pIL12 with electroporation (yes, that's electric shock) on a six-week cycle. (Our next-door neighbor, a genetic scientist, calls me a human GMO.) The gene therapy regimen is designed to make my tumors more likely to respond to the second part of my treatment: Despite it's not being approved by the Food and Drug Administration for my type of cancer, I have received infusions since January of Keytruda (pembrolizumab), the immunotherapy drug taken by Carter

One new tumor has appeared, under my left arm, but all other detectable cancer has vanished. A golf-ball-size lump under my right arm shrank and then was nowhere to be found. A lesion on my spleen has gone missing. Most signifi cantly, a cancerous "large neck mass" that was positioned to kill me quickly — it had doubled in size as of last December — not only stabilized in April, a recent PET scan showed all signs of cancer in this area to have simply disappeared.

I feel fi ne. I live well, though scan-to-scan. Nobody knows how long the good news will last for me or other cancer patients who are responding to immunotherapy. But some have already survived for years after their predicted deaths. Like me they probably feel a miraculous gift — unanticipated time of unknown duration — has been dropped into their laps.

It is true that a cheerless outlook remains for mostpatients with any type of cancer that has metastasized in the body. Immunotherapy regimens don't exist for all types of cancer, and wrenchingly, many patients who could be helped can't get access to drugs and clinical trials that could make a difference for them. Finally, for some patients who seem like a good match for the therapies, the treatments simply don't work. Nobody knows why. Not yet.

Still, after decades of failed promises to "cure" cancer, it's easy to understand why research oncologists are feeling optimistic right about now. They have real hope. It's possible patients of the future will experience cancer as something more like a chronic disease, a frightening but manageable illness as opposed to the indiscriminate killer that now enters the lives of 14 million people worldwide every year.

My place in the timeline of these changes is at the inception, and there is much yet that is not understood. My treatments are stretching the good time I have left, not lifting my death sentence. I am still coming to terms as best I can with my own unequivocal transience.

But no, I'm not dead yet.

When people are surprised to see me, I tell them I'm among the early fortunate. I am grateful each day for my husband, family and friends. Facing death on a close horizon has heightened my awareness that our time on Earth is fi nite. But quite unexpectedly it has also made me a living, breathing advertisement for humanity's hopeful new edge on cancer.

Melinda Welsh was founding editor of the Sacramento News & Review. She is leading a national writing project about climate change, www.letterstothefuture.org

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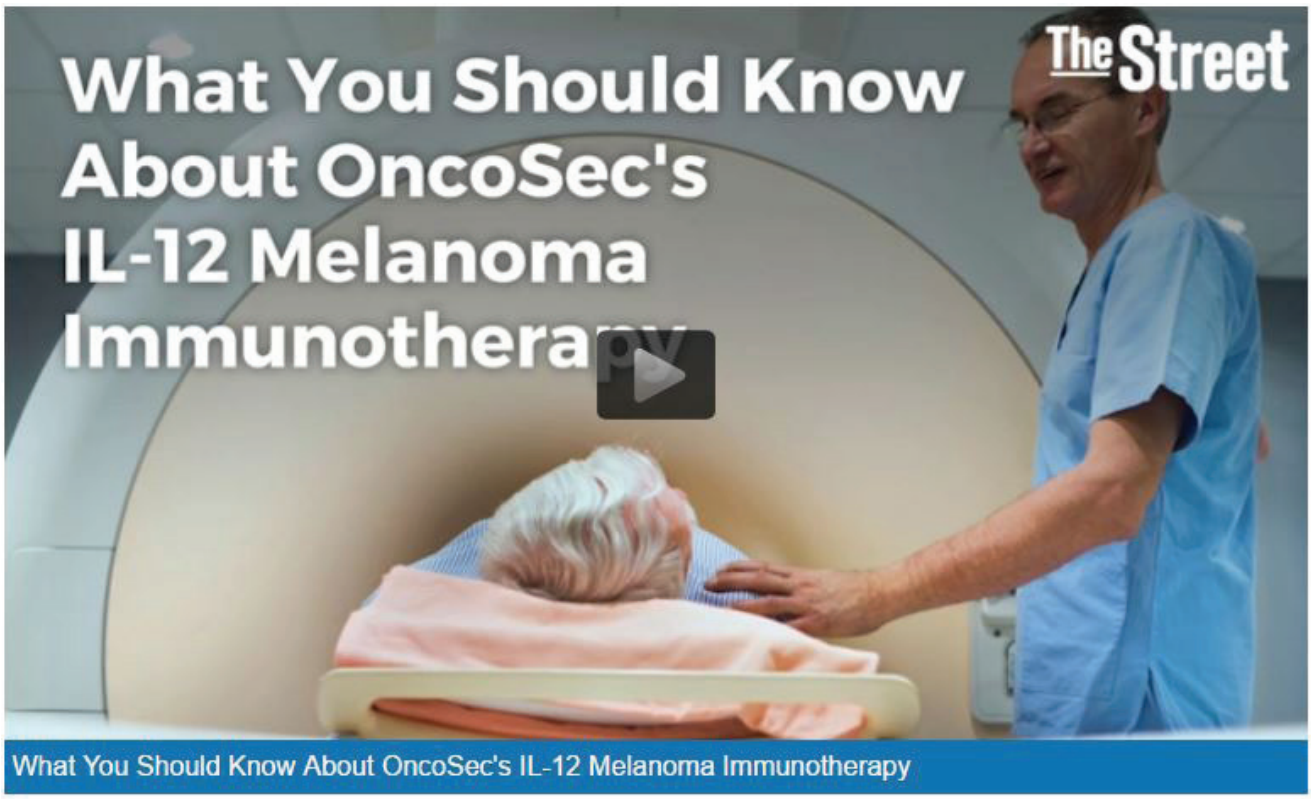
Nobody knows how long the good news will last for me or other cancer patients who are responding to immunotherapy. But some have already survived for years.

TheStreet

Biotech Stock Mailbag: OncoSec Medical and the Quest to Turn Cold Tumors Hot

TheStreet's Adam Feuerstein answers reader questions about biotech stocks.

Adam Feuerstein Follow Mar 3, 2017 7:33 AM EST



This week, I will take a closer look at a new approach in cancer immunotherapy from a tiny biotech company -- OncoSec Medical (ONCS) .

Before I get started, a word or two of caution: OncoSec is a micro-cap biotech company with a single-digit stock price and an enterprise value of just $2.7 million. As of October, the company had $24 million in the bank and is spending about $4 million to $5 million per quarter.

I might actually say a few nice things about Oncosec. Don't pass out from shock. Don't accuse me of pumping, either. Take the risk seriously.

All right with that said ...

At the risk of sounding too dismissive about OncoSec's IL-12 cancer immunotherapy, there was a single patient's worth of intriguing data in the melanoma study presentation made last week. That's from a study of 22 patients. The complete response to Oncosec's IL-12 therapy seen in that single melanoma patient -- who had previously progressed on Merck's (MRK) Keytruda -- is interesting enough to push the development of the product forward, but the data on the other 21 patients looked, to me, inconclusive. Not negative, per se, but hard to interpret.

OncoSec is among the scores of drug companies trying to find a solution to a biologic roadblock that, to date, has limited the efficacy of checkpoint inhibitors like Keytruda or Bristol-Myers Squibb's (BMY) Opdivo to a minority of cancer patients.

Checkpoint inhibitors work by releasing the brake on the immune system, so these drugs are most effective against "hot" tumors already studded with T cells and other immune cells.

"Cold" tumors are largely resistant to checkpoint inhibitors because they lack signifi cant engagement by immune cells. To extend the analogy, releasing the brakes without an engine present doesn't get you very far.

How to turn "cold" tumors into "hot" tumors? OncoSec's approach is to inject "cold" melanoma lesions with DNA-based interleukin-12 (IL-12), a protein that activates components of the immune system. OncoSec then uses a short series of electric shocks (delivered with needles) to open the membrane of the tumor cells and help the IL-12 to enter.

With that (rather long) introduction, let's get to the OncoSec data. You can download a presentation here.

The company conducted a phase II study involving 22 patients with melanoma predicted to be unresponsive to checkpoint inhibitors using two different biomarker assays. All the patients were treated with a series of pulsed IL-12 injections directly into their melanoma lesions followed by standard intravenous delivery of Keytruda.

After 24 weeks, the overall response rate to the IL-12/Keytruda combination therapy was 41%. Five patients achieved a complete response, four patients had a partial response. (Another patient had stable disease at 24 weeks but achieved a partial response at around one year.)

OncoSec is excited about the 41% response rate from the IL-12/Keytruda combination because it's higher than the 33% response rate typically seen with Keytruda alone in melanoma patients. The patients enrolled in the study had melanoma lesions deemed unlikely to respond to Keytruda, which makes the 41% response rate even more encouraging from OncoSec's perspective. There's also evidence collected in the study showing IL-12 increases immune cell involvement in the tumors.

But (and you knew there was going to be a but)....

The two biomarker assays used to identify melanoma lesions unlikely to respond to checkpoint inhibitors have not been approved or prospectively validated (although they are published.) This means OncoSec cannot be entirely confi dent the melanoma patients enrolled in its phase II study would not have responded to Keytruda alone.

The study also lacked a control arm, which makes interpreting results tricky.

For these reasons, the 41% overall response rate observed in the IL-12/Keytruda study is probably skewed high.

The best method to test the ability of OncoSec's IL-12 to turn cold tumors hot would be in patients with melanoma that didn't respond (or progressed) following an initial course of checkpoint inhibitor treatment.

There were nine patients in the OncoSec study previously treated with a checkpoint inhibitor. Among those nine patients, a single patient had a complete response following treatment with pulsed IL-12 and Keytruda. That patient also entered the study with a melanoma lesion that tested "cold" on the two biomarker assays.

(A second patient had a partial response to IL-12/Keytruda but the results of the biomarker assays were inconclusive.)

That one melanoma patient wasn't likely to achieve a complete response based on baseline characteristics and previous treatments, but he or she did. That's really interesting and suggests IL-12 may have played a role in turning a cold tumor hot. But a single patient's worth of data is far from conclusive. It could be a mirage.

The next clinical trial proposed by OncoSec will also evaluate the combination of IL-12 and Keytruda but enroll only patients with melanoma that failed to respond to checkpoint inhibitors.

That's the best patient population to enroll, although including a control arm is not in the plans. Too bad. I can see why designing a study with a control arm would be difficult the effort would yield stronger, more convincing data, if IL-12 is doing what OncoSec hopes it is.

The company is suggesting this next phase II study might be sufficient to get IL-12 approved by the FDA, if positive. I would be skeptical about such a promise until the company gets something in writing from the FDA.

There are a few additional risk and limitations to consider about OncoSec's cancer immunotherapy approach. The electrically pulsed IL-12 must be injected directly into tumors, which could limit the addressable patient population. The electrical pulsing procedure isn't trivial. It hurts. OncoSec's presentation was light on details about IL-12's safety profile. Lastly, there is a lot of competitors trying to improve cancer immunotherapy in ways that could be better or easier to administer than OncoSec's IL-12.

I'm intrigued enough by the single patient with the complete response too IL-12/Keytruda to be interested in seeing more from OncoSec in the future.

Adam Feuerstein writes regularly for TheStreet. In keeping with company editorial policy, he doesn't own or short individual stocks, although he owns stock in TheStreet. He also doesn't invest in hedge funds or other private investment partnerships. Feuerstein appreciates your feedback; click here to send him an email.

5820 Nancy Ridge Dr, San Diego, CA 92121
(858) 210-7333
media@oncosec.com