REFINITIV STREETEVENTS

EDITED TRANSCRIPT

DMTK.OQ - Q2 2023 DermTech Inc Earnings Call

EVENT DATE/TIME: AUGUST 03, 2023 / 9:00PM GMT

REFINITIV

CORPORATE PARTICIPANTS

Steve Kunszabo *DermTech, Inc. - Senior Director, IR*

Bret Christensen *DermTech, Inc. - President & CEO*

Kevin Sun *DermTech, Inc. - CFO*

CONFERENCE CALL PARTICIPANTS

Thomas Flaten *Lake Street Capital Markets - Analyst*

Albert Hu *Craig-Hallum Capital Group - Analyst*

PRESENTATION

Operator

Good day, and thank you for standing by. Welcome to DermTech's second-quarter 2023 financial results call. (Operator Instructions) Please be advised that today's conference is being recorded.

I would now like to hand the conference over to your speaker today, Mr. Steve Kunszabo, Sir, please go ahead.

Steve Kunszabo - *DermTech, Inc. - Senior Director, IR*

Thank you, operator. Welcome to DermTech second-quarter 2023 earnings call. With me on today's call are Bret Christensen, our President and Chief Executive Officer; and Kevin Sun, our Chief Financial Officer.

Our call today will include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements made on this call that do not relate to matters of historical fact are considered forward-looking statements. Forward-looking statements made during this call, including projections of future performance are based on management's expectations as of today, and are subject to various factors, assumptions, risks and uncertainties, which change over time. Actual results could differ materially from those described in such statements. Several factors that may contribute to or cause such differences are described in today's press release and our most recent filings with the SEC. We undertake no obligation to update these statements except as required by applicable law.

Our second quarter 2023 earnings press release and SEC filings are available on our Investor Relations website. A transcript of today's call will be available on our website later today.

With that, let me turn things over to Bret.

Bret Christensen - *DermTech, Inc. - President & CEO*

Thank you, Steve, and thank you, everyone, for joining us. It's been a whirlwind since I joined DermTech in early May. I'd like to start with what excites me about leading DermTech before I jump into the details of how we'll do some things differently moving forward.

First, we have a great technology that should be a key tool for health care providers. The current standard of care is challenging with the solutions that have been traditionally available to clinicians. But we believe it needs to be better than performing 20 or more invasive surgical biopsies to find just one melanoma.

Melanoma is the most aggressive form of skin cancer and claims 8,000 lives annually in the US. The DermTech Melanoma Test, or DMT, is non-invasive, rules out melanoma with a 99% negative predictive value, and provides clinicians with objective and actionable genomic data for suspicious lesion.

My vision is for the DMT to be deployed universally as part of the melanoma care pathway, and we have an excellent product to execute against this goal.

Second, we're pursuing a large addressable market where significant patient need exists. Approximately 200,000 new cases of melanoma are reported every year in the US, resulting in $3.3 billion in annual treatment costs. We can help lower these costs by ruling out the need for unnecessary surgical procedures while also providing a better patient experience that may encourage testing suspicious lesions earlier.

This is important because early-stage diagnosis has a five-year survival rate of 99%, whereas a late-stage diagnosis drops the survival rate significantly to 30%. Genomic changes may perceive visual changes from melanoma, and the DMT detects genomic markers that are correlated with an increased risk for melanoma and can aid decision-making by clinicians.

Third, we're making solid progress with insurance providers, expanding access to our tests but still need to reinforce our message around the clinical and health economic benefits of the DMT and improve our onboarding process once we complete agreements.

Many payers that have comprehensively reviewed the most current data have issued favorable coverage policies and signed agreements during the last several months. We've expanded covered lives approximately 45% to $133 million in 2023 and now work with seven of the top 10 Blues plans and two large governmental payers. These steps expand access to the DMT as an in-network benefit and improved reimbursement. Overall, we've made good progress but must continue to be focused on payers.

Based on our coverage today, we reach approximately 45% of total covered lives in the US. We have a strong foundation that aligns with our intense focus on prioritizing reimbursed tests and boosting revenue. Our covered lives footprint, coupled with the fact that less than a third of our total billable sample volume is reimbursed today clearly supports the path to monetizing the significant DMT volume we already have.

For example, if our annual volume stayed relatively flat at the 2022 level of roughly 68,000 tests, but we doubled the percentage of these tests for which we are reimbursed. Our test revenue could more than double from the approximately $14 million we generated last year. We are okay, with trading some volume growth in the short term for a healthy average selling price or ASP and revenue gains.

We'll prioritize test volume again when we further -- when we're further down the path of sustained revenue growth. In addition to our coverage wins, we've received a favorable recommendation from ECRI, a well-recognized non-profit technology assessment firm. ECRI is focused on healthcare technology evaluation and safety to improve quality, reduce costs, and achieve better outcomes across all healthcare settings. We believe this favorable recommendation could further influence coverage decisions by commercial payers.

Our visibility with payers also improves through state legislative efforts. Bills mandating insurance coverage of genomic testing or so-called biomarker bills are expected to be effective in several additional states in late 2023 and early 2024. Lawmakers across the US have advocated for improving access to potentially life-saving genomic tests.

Our TRUST 2 study, which we initiated in 2022, should provide additional real-world evidence in support of ongoing payer discussions. This is a prospective study designed to follow a cohort of 2,000 to 3,000 patients with negatively tested lesions for up to one year. The study also assesses the histopathologic diagnosis of up to 1,000 lesions that tested positive with the DMT.

We expect to release top-line results in the second half of 2023. The resulting data positive can support reengagement with many payers. Across the organization, we've made some tough decisions to streamline operations and put all our energy into scaling the DMP and prioritizing reimbursed tests to grow revenue. Building a strong foundation by having success with the DMT has to come first.

We believe in the power of our non-invasive skin genomics platform and recognize that has a broad array of applications in dermatology, but we need to win with the DMT before we consider these other opportunities. The DMT's ASP and test revenue were both up sequentially in the quarter, which is a good start, as we reposition the business around this new strategy, but we have more work to do. We're starting to make some adjustments, especially around the tactics we're deploying to generate reimbursed tests and maximize revenue.

First and perhaps most importantly, we've aligned incentive compensation for our sales team with driving reimbursed tests and revenue over total volume. In addition, we've extended payer mix and analytics reporting to allow the field team to target providers with reimbursed billable samples based on our already healthy demand.

Second, we've dissolved certain territories and merged others to focus on reimbursing samples where we already have broad insurance coverage. Over the last two quarters, we've trimmed our sales team from approximately 70 -- roughly 60 reps to facilitate this objective.

Third, we're going to shift our spending more closely to sales team enablement rather than broad-based marketing efforts. We still plan to participate in national dermatology conferences, but our presence at regional conferences will be more targeted based on several factors. We'll also recalibrate our direct-to-consumer marketing tactics to capitalize on areas where we already have insurance coverage. We need to build DMT adoption at the ground level with clinicians, and this change in our approach should improve traction in communicating the DMT's value proposition.

Lastly, we've realigned our support infrastructure, including concierge services and medical affairs support in territories where we have insurance coverage for DMT. We've also improved the integration of electronic health records with our customers, which significantly reduces billing friction and increases the success rate of appeals with payers.

In closing, we believe we've now right sized the business across all functional areas and sharpened our focus. Our capital and energy are concentrated on three key priorities; prioritizing reimbursed tests over total volume to grow revenue, continuing to expand coverage for the DMT, and sustaining our cash runway.

We'll scrutinize every dollar we spend to ensure it supports achieving these goals and generate a strong return. I'm excited to have joined DermTech three months ago to lead this great team, and I look forward to the many successes ahead of us.

With that, let me turn the call over to Kevin for more detailed financial review.

Kevin Sun - *DermTech, Inc. - CFO*

Thanks, Bret. Good afternoon, everyone. I'll start by reviewing our key financial and operating metrics for the second quarter, then summarize how we're thinking directionally about our outlook for the back half of 2023. I'll conclude by outlining our liquidity profile and cash runway targets.

Total sample volume declined 5% year over year and 2% sequentially for the second quarter to approximately 17,450. The decrease resulted from our prioritization of reimbursed tests, and as we noted last quarter we stopped testing samples from pediatric patients and certain Fitzpatrick Skin Types based on guidance from our lab accrediting organization

Test revenue was down 14% year over year to $3.6 million, largely due to a $0.3 million downward revenue adjustment resulting from changes in collection estimates for tests run in prior periods, as well as lower billable sample volume. Test revenue was up 4% sequentially on higher ASP and lower prior period adjustments.

Contract revenue was $0.4 million during the second quarter, up from $0.1 million in the year-ago period. The increase is from new agreements with two large biopharma customers. It's important to remember that high-margin contract revenues remain uneven as it's linked to the clinical trial progress of our biopharma customers. Nonetheless, these deals are a great way to increase awareness and usage of our Smart Sticker technology.

Total revenue for the second quarter fell 6% year over year to $4.0 million, primarily on lower test revenue. Total revenue was up 14% sequentially on higher contract and test revenue.

Drilling into our test revenue drivers, first, ASP was $204 per sample in the second quarter, down 10% year-over-year, but up 6% sequentially. Medicare ASPs continue to trend higher due to better collection success and the Medicare proportion of billable sample volume grew sequentially from 23% to 25% in the second quarter of 2023.

Certain non-contracted commercial payers continue to reduce their payment rates, leading to downward adjustment for the quarter. Normalizing for prior period adjustments, second quarter ASP would have been $221, which was up modestly on a sequential basis.

We still expect variability going forward, primarily due to the lag in recognizing financial benefit from new payer coverage and fluctuating payments from non-contracted commercial payers. In cases where we've seen both a favorable coverage policy and a signed agreement in the first half of 2023, we believe we're wrapping up the final administrative steps to start getting paid.

Second, we had approximately 2,420 unique ordering clinicians in the second quarter, down 5% from the first quarter. With approximately 4,350 unique ordering clinicians during the last 12 months, we penetrated 48% of our current target market of 9,000 dermatology clinicians.

Third, our average quarterly utilization or average number of tests ordered per unique ordering clinician was up sequentially to 7.2 billable samples in the second quarter versus 7.0 in the first quarter and 7.7 in the year-ago period.

Focusing next on operating expenses. Cost of test revenue was $3.9 million, a 21% year-over-year increase, yielding a test gross margin of negative 10%. The increase in cost of test revenue was primarily due to higher infrastructure costs from our new lab and higher materials expenses.

Sales and marketing expenses were $13.0 million, which is 13% lower than the previous year. The decrease was largely attributable to reduced marketing expenditures. Research and development expenses were $3.9 million, a 44% decline from the year-ago period, primarily due to lower employee-related and clinical study costs. General and administrative expenses were $15.2 million, $6.3 million, or 71% higher compared to the second quarter of 2022.

The increase was driven by approximately $2.9 million of additional non-cash stock-based compensation expense and $0.5 million of severance costs related to our former CEO's departure, approximately $2.1 million in non-recurring restructuring charges, and approximately $1.2 million from increased infrastructure costs related to our new facility. The entire restructuring charge was booked to G&A, even though the restructuring actions also included the sales and marketing functions.

Fourth quarter of 2023 will be the benchmark moving forward and will set a new run rate for operating expenses. We expect that the third quarter of 2023 may have limited costs from winding down certain programs. Net loss for the second quarter was $31.4 million, which included $7.5 million of non-cash stock-based compensation expense compared to a net loss of $29.6 million for the same period of 2022, which included $4.8 million of non-cash stock-based compensation expense.

Moving now to our 2023 outlook. We continue to anticipate DMT volumes in 2023 will be relatively flat compared to last year due to our prioritization of reimbursed tests. ASP and test revenue have begun to slowly tick up, and we plan for full-year ASP and test revenue to increase when compared to 2022. Providing specific guidance remains difficult due to potential additional delays related to recent coverage wins and possible tightening by non-contracted payers.

As Bret noted, we're okay trading some volume growth in the short term for healthy ASP and revenue gains. We anticipate emphasizing volume growth again when we have reached a meaningful revenue inflection point.

And lastly, a review of our liquidity profile and balance sheet. At quarter end, we had cash, cash equivalents, restricted cash, and marketable securities of $89.7 million, which includes net proceeds of approximately $4.5 million from stock issuances under our at-the-market or ATM facility during the period. Based on the expected $25 million to $30 million in annualized cost savings from our restructuring actions, we believe we now have cash runway into the first quarter of 2025.

In addition to the significant expense savings, driving ASP and revenue as a key factor that helps preserve and even extend our cash runway. If ASP and revenue grow during the rest of 2023 and through 2024, we have the potential to push our cash runway out even further. In summary, we're making solid progress in reorienting our effort around winning with the DMT. and growing revenue and have extended our cash runway.

Now I'll turn the call back to Bret.

Bret Christensen - *DermTech, Inc. - President & CEO*

Thanks, Kevin. Before we wrap up and move to Q&A, I'll share an especially powerful patient story that encapsulates why I joined DermTech. One of our sales reps was recently training the physician staff on how to apply our Smart Sticker correctly at an office where the doctor hadn't previously used the DMT.

The physician volunteered to apply the DMT on one of his own lesions that he and his colleagues believe did not look like melanoma but was ambiguous. The test came back double gene positive, indicating a strong correlation with melanoma. A biopsy of the lesion was then sent to two pathologists who determined it was Stage 1 melanoma. Importantly, the doctors shared with us that the lesion that was identified as melanoma looked nothing like hundreds of lesions he's previously diagnosed in his career.

This story captures the critical need for precision genomics as cancer is a disease of the genome and the current visual assessment standard is challenging even for an expertly trained medical professional. The physician's lesion has since been excised and he's credited us with potentially saving his life. He's also begun using the DMT in his practice.

Now I'll turn things back to the operator for Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Thomas Flaten, Lake Street Capital Markets.

Thomas Flaten - *Lake Street Capital Markets - Analyst*

Hey, thanks for taking the question, guys, and congrats on the quarter. Kevin, I was wondering if you could help us think through how we should think about gross margins. You've obviously got the new facility to account for, but your ASPs should grow as you focus on profitable test volume. Can you just help us think through that?

Kevin Sun - *DermTech, Inc. - CFO*

Yeah. As expected, the increase in the per test COGS was primarily due to those higher infrastructure costs for our new lab. Wages were also higher. But now that we've moved into the new lab, we're working on various initiatives to reduce COGS going forward. As you know, gross margin is a combination of per unit COGS as well as ASPs. And because we have a challenge estimating ASPs with the delays tied to onboarding new coverage, we're not kind of ready to give a margin forecast. But what we can say is we are committed to reducing these COGS going forward.

And as we said before, because of our test, the primary PLA as a 2-gene assay using PCR technologies. We have opportunity to reduce it from the $200 roughly that it is now. But we're just not ready to give specific guidance because it's a combination of both those items, ASP improvement as well as per unit cost reduction.

Thomas Flaten - *Lake Street Capital Markets - Analyst*

Got it. And then I was wondering if I could ask you to comment on the new territories and there was some noise on the line, but I think you said you were down to 60 territories now. Could you give a sense of percentage-wise, or some other way what the coverage looks like in these kind of idealized territories where you do have better coverage?

Bret Christensen - *DermTech, Inc. - President & CEO*

Hey, Thomas, it's Bret. So what we did is we said we went from roughly 70 territories a few quarters ago to around 60 today. And the point of that really is to align those territories where we do have our best reimbursement. And so it varies with each territory, but certainly, Medicare is universal and is out there in every territory.

And then the commercial payers just varies by territory, which is why we did dissolve and merged a few territories as well to get down to that number. We'll look to expand in the future, maybe as coverage does change and improve in some of those areas. But for now, we just believe the ROI on that spend with the sales force is best where we've got the commercial coverage as well as Medicare. And so we better aligned the territories, but we've also provided that information so that reps appropriately target the right physicians with the right mix of coverage.

Kevin Sun - *DermTech, Inc. - CFO*

Yeah. And it definitely varies state by state and territory by territory, but some of the best coverage on a specific territory basis with Medicare as well as kind of say the local regional Blues Plan, we might have 70%, 80%, or more percent of covered lives in that area.

Thomas Flaten - *Lake Street Capital Markets - Analyst*

Excellent. I appreciate you guys taking the questions. Thank you.

Operator

(Operator Instructions) Alex Nowak, Craig-Hallum Capital Group.

Albert Hu - *Craig-Hallum Capital Group - Analyst*

Hi, good afternoon, everyone. This is [Albert Hu] on for Alex. So one of the biggest challenge for DermTech has been getting the big national payers on board. Bret, with this being your first full quarter being at DermTech, can you walk through how you're restructuring the clinical impaired teams to push for those coverage wins?

Bret Christensen - *DermTech, Inc. - President & CEO*

Yeah. Sure, Albert. Thanks for the question. Let me start, though, by saying one of the things I said when I got to DermTech is I was actually quite impressed with the level of covered lives that we already had achieved. And while the big commercial payers are going to be important to us, and we continue to have really good discussions with those payers, we have 133 million covered lives today. And this new focus is around continuing to drive those covered lives higher but also really making sure that we get our fair share of reimbursed tests in the door that more closely mirrors the covered lives, which is currently at about 45%.

So 45% of covered lives, but again, less than a third of the tests we get today are from those payers and reimbursed. So that's the short-term focus. As far as the conversations and progress with the national payers, we believe they're going to come around. And where we get payers to look at our most recent health economic data, it's very convincing. And so these things take time, and we'll continue to have good conversations with those payers.

We did get some negative policy decisions from a few of them earlier this year, but we have chances to go back with ECRI, but also when we release TRUST 2 data later this year. And so we're optimistic we're going to get there. For now, we've got really, really strong reimbursed lives out there. We just need to make sure that, that really closely mirrors the tests that are in the door, and that's going to be the focus in the short term.

Albert Hu - *Craig-Hallum Capital Group - Analyst*

Okay. Got you. And an item we've heard from clinics is how to fit DMT into the practice. So what sort of marketing changes are you making in regard to this?

Bret Christensen - *DermTech, Inc. - President & CEO*

Yes, Albert, I can take that one as well. So the message is really important. And one thing I've learned in my short tenure at DermTech is the value proposition to me is really clear, and we need to tell a really convincing story to dermatologists in the office setting that look, this is what I said in my remarks, this is a tough thing to do to find melanoma, and it's why we believe dermatologist err on the side of a lot of biopsies you don't want to miss melanoma in the office setting.

There's also -- because of that there's a lot of lesions, they don't want to biopsy where there's cosmetically sensitive areas. Some of those that they'd prefer to photo and follow. But again, to be safe, you end up doing a lot of biopsies to make sure you don't miss melanoma. That tells me there's a clear place in every practice for the DermTech melanoma test. And that's what we're starting to get some early utilization in those areas, and we'll look to expand later on.

But look, this is some this is a win-win for everybody. We want to work with dermatologists and not against them in integrating this into their practice. And to me, there's a clear value proposition for some of those edge cases where -- that they're hesitant to biopsy.

Albert Hu - *Craig-Hallum Capital Group - Analyst*

Got it. And I got two more questions here. So during the call, you mentioned some of the sales structure changes in rep compensation after you joined the company. Can you reiterate that part?

And the second question is can you give us the latest again on the clinical trials, what new study readouts should we expect this year and next year? I know you touched on this during the call, but just to reiterate this for me, please? Thank you.

Bret Christensen - *DermTech, Inc. - President & CEO*

Yes, sure. So the incentives that I mentioned in the opening remarks is really about -- I specifically called out sales rep incentives. But honestly, the incentives across the organization have been aligned to revenue. And the change there is simply that early on, the focus was volume, and we've spoken a lot about volume in previous earnings calls. And that was the right move, honestly.

You've got to drive volume. You've got to show demand. You've got to show payers there's demand for your product in the marketplace. You've got to get dermatologists comfortable with using your product, and you've got to get patients aware. And all of that means volume is really critical early on in a product life cycle like the DermTech Melanoma Test.

Now, though, with 45% of covered lives, the focus for us is going to be around revenue. And so we've simply just aligned incentives to that end. And specifically, the sales force that I called out in my opening remarks, have a new comp plan that is based off of revenue and not just volume.

What that's going to do is that's going to force all of us to have the difficult conversations or more difficult conversations with dermatologists to make sure that it's being used in the right way that we're getting more of those reimbursed tests in the door. And that's going to be -- again, the focus in the short-term, it's probably the most immediate change that needed to happen. And I think it also just facilitates the improvement of the message and the value proposition. And so that's what we've done in the field to change that.

Also, as far as the clinical data, Kevin probably has some things to add here. The one thing I called out in my opening remarks was TRUST 2, which is that prospective trial of 2,000 to 3,000 patients looking at a negative DMT result and following those patients for up to a year. We anticipate doing a top-line readout sometime later this year, by the end of the year. And again, that's going to be an opportunity for us to go back and revisit the conversation with payers that have given us a negative coverage decision.

Kevin Sun - *DermTech, Inc. - CFO*

Yeah. And as we mentioned, too, due to changes in guidance from our accrediting organization, we stopped testing samples from pediatrics. And so we did kick off a utility study around pediatrics to try to gather more data. Melanoma is very rare in the pediatric population. But obviously, a non-invasive approach using genomics like the DMT allows for is a very good candidate for our usage.

Albert Hu - *Craig-Hallum Capital Group - Analyst*

Thank you, guys.

Operator

(Operator Instructions) Andrew Brackmann, William Blair.

Unidentified Analyst

Hi, guys. This is Dustin online for Andrew. Just the first question I want to ask about the biomarker bills you mentioned that are being considered by lawmakers. Just what impact would those have potentially on volumes in ASP if that legislation gets passed? And what states would be most impacted there?

Bret Christensen - *DermTech, Inc. - President & CEO*

Hey, Dustin, this is Bret. It's a fluid situation. And -- there are many states that have either planned, proposed, or passed legislation around requiring health insurance companies to cover tests that offer critical biomarkers. And so if you look at the language and the number of states that are actively involved in this already, the language of those bills vary state to state, and there's many that are in some process along the way to pass legislation.

The count is probably around 18 to date, but it's a growing list and pretty fluid. It's an opportunity, again, for us to go back to the table with many payers that haven't covered, and it will certainly be a push from a legislative standpoint to cover these types of tests.

Unidentified Analyst

Understood. And then just two more financial questions for us. In light of the restructuring at the midpoint to 27.5% annualized OpEx savings, can you just walk through where the reductions will be kind of by OpEx item? Kevin, you mentioned the fourth quarter is going to be the real run rate that we should expect. So where should that be? And then second, you tapped the ATM in the quarter. How should we think or see you guys using that facility going forward from here? Thank you.

Kevin Sun - *DermTech, Inc. - CFO*

Yeah. As we mentioned, the restructuring affected really most departments across the organization. So while the charge itself was booked into G&A, there was impacts and effects on sales and marketing, and even within the financial results for the quarter, you could see the R&D expenses

are trending down. So the restructuring, again, a big part of it was the prioritization of DTM, and with the suspension of pipeline activities and programs that has a natural impact on the R&D line.

And then with the changes to the commercial focus that Bret outlined and the reduction of broad marketing type of initiatives versus very more targeted and sales force enablement, there will be impacts on the sales and marketing line. But it's really all up and down the OpEx line items.

On the ATM, so we've taken the important steps to reduce that cash burn through those operating expense reductions as part of the restructuring and our focus on improving reimbursed test volumes. The ATM, it's one of the lowest cost of capital options in the current environment. And since valuations are fluid, we've used the ATM to provide some flexibility as we evaluate strategies and options to capitalize the business in a thoughtful way. We'll continue to be mindful of relevant considerations as we evaluate deploying the ATM in the future.

Unidentified Analyst

Okay. Great. Thank you, Kevin. That's it from us.

Operator

Thank you. This will conclude the Q&A session of the conference, and this also concludes the conference call itself. Thank you all for participating. You may now disconnect and have a pleasant day.
